UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

This Amended Petition applies to:

THE CHEROKEE NATION,

Plaintiff,

-against-

PURDUE PHARMA L.P.; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY INC.; PURDUE PHARMA MANUFACTURING INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; ENDO PHARMACEUTICALS, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO INTERNATIONAL PLC; PAR PHARMACEUTICAL, INC.; PAR PHARMACEUTICAL COMPANIES, INC., F/K/A PAR PHARMACEUTICAL HOLDINGS, INC.; ALLERGAN PLC F/K/A ACTAVIS PLC; ACTAVIS, INC. F/K/A WATSON PHARMACEUTICALS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. F/K/A WATSON PHARMA, INC.; BEVERLY SACKLER; JONATHAN SACKLER; KATHE SACKLER; DAVID SACKLER; ILENE SACKLER LEFCOURT; MORTIMER SACKLER; RICHARD SACKLER; THERESA SACKLER,

Defendants.

Case No. 18-CV-236-RAW (E.D. Okla.); (Sequoyah County, Oklahoma No. CJ-2018-86)

Case No. 1:17-md-2804
Case No. 1:18-op-46325

Judge Dan A. Polster

JURY TRIAL DEMANDED

AMENDED PETITION[1]

1. The Cherokee Nation, through Attorney General Todd Hembree, brings this civil action under the statutory and common law of the Cherokee Nation, and the law of the State of Oklahoma where applicable, for injunctive relief, compensatory damages, statutory damages, punitive damages, civil penalties, and any other relief allowed by law against the Defendants that, by their actions, have knowingly or negligently marketed and promoted prescription opioid drugs and have knowingly or negligently manufactured and distributed prescription opioid drugs within the Cherokee Nation in a manner that foreseeably injured, and continues to injure, the Cherokee Nation and its citizens.

2. There is a devastating epidemic of prescription opioid abuse sweeping through the Cherokee Nation and across the United States. It is an epidemic of unprecedented proportions, leaving in its wake a substantial loss of public and private resources and heartbreaking addiction, disability, and death. Indeed, on October 26, 2017, the President of the United States declared the opioid epidemic a public health emergency.[2]

3. Today in the Cherokee Nation, and everywhere else in the country, prescription opioids kill more people than heroin. The National Center for Health Statistics reported that prescription opioids killed 22,598 people in the United States in 2015, as compared to 12,989 deaths from heroin. Prescription opioids are the driving force behind skyrocketing rates of drug overdose deaths, which now surpass car accident deaths nationwide. And as the former U.S. Surgeon General stated during his 2016 visit with tribal representatives in Oklahoma – where

[1] By filing this Amended Petition, Plaintiff does not consent to jurisdiction in federal court. Plaintiff's motion to remand the action to Oklahoma state court remains pending. Pursuant to the MDL Court's orders, Dkts. 1515 & 1680, Plaintiff is filing this Amended Petition prior to or on August 12, 2019. By doing so, Plaintiff does not waive any argument that this matter should be remanded to state court.

[2] Julie Hirschfeld Davis, *Trump Declares Opioid Crisis a 'Health Emergency' but Requests No Funds*, N.Y. Times (Oct. 26, 2017), https://www.nytimes.com/2017/10/26/us/politics/trump-opioid-crisis.html.

most Cherokee Nation citizens reside – the "prescription opioid epidemic that is sweeping across the U.S. has hit Indian country particularly hard."

4. The brunt of the epidemic could have been, and should have been, prevented by the Defendant companies – the manufacturers of some of the most popular and profitable prescription opioid drugs, including OxyContin, Fentora, Actiq, and generics like oxycodone. Yet despite all of the known dangers of OxyContin and other opioid drugs they have produced, the Defendant companies have employed long-running, deceptive, and deceitful marketing campaigns, advocating for the drugs' expanded use while downplaying or outright misstating the dangers of opioid drugs, and by allowing opioids to be diverted into improper channels to fuel the epidemic. Those efforts have led to billions of dollars in profits for Defendants – but at a terrible cost to the Cherokee Nation, which has become flooded with prescription opioids and has had to incur the costs of increased health care expenditures, crime, and social ills resulting from prescription opioid abuse, addiction, and diversion.

5. Opioids have been a commercial triumph for Defendants,[3] one born out of canny marketing first initiated by Defendants Purdue Pharma L.P., Purdue Pharma Inc., The Purdue Frederick Company Inc., and Purdue Pharma Manufacturing Inc. (collectively, "Purdue"). Purdue was not the inventor of the powerful generic opioid oxycodone; in fact, the active ingredient in OxyContin, oxycodone, has been in clinical use since 1917.[4] But Purdue took an old drug, repackaged it for modern use, and then, beginning in 1996, marketed the drug extensively throughout the medical community with claims that were misleading, deceptive, and contrary to the established clinical understanding of the drug. Seizing on an opportunity to make

[3] Throughout this petition, when reference is made to Defendants, this includes the officers, agents, or employees of Defendants, as well as predecessor and successor entities to the named Defendants. Individual Defendants refers to the named individuals in this petition.

[4] Eija Kalso, *Oxycodone*, 29 J. Pain and Symptom Mgmt. S47, S47 (May 2005).

profits, Purdue also repackaged other old opioid drugs and have marketed them in a similar manner, worsening the epidemic. It was not long before all Defendants followed suit and engaged in similar marketing tactics. Defendants have profited handsomely from improperly marketing prescription opioids to an ever-larger population of physicians and patients for a range of pain relief. They have done so while obscuring the fact that OxyContin and other prescription opioids produced and distributed by Defendants are dangerous and addictive when used for general pain management and relief. Defendants deliberately conceived of their strategy, creating an entirely new narrative surrounding the use of opioids bereft of scientific support, to encourage the use of opioids by those suffering from common chronic pain conditions.

6. Defendants' years-long marketing campaign advocating for the prescription of opioid drugs to treat a large range of chronic pain – in contravention of scientific and medical findings against the use of opioids for such pain – has resulted in the vast overprescribing and distribution of prescription opioids. Those overprescribed opioids are the drugs that have fueled the opioid epidemic in the Cherokee Nation.

7. Defendants also have failed in their role as the first gatekeepers in the controlled substance distribution chain. Each registered party in that chain has a duty to serve as a "check" in the drug delivery system by securing and monitoring opioids at every step as they travel through commerce, protecting them from theft, and refusing to fill suspicious or unusual orders by downstream distributors, pharmacies, and patients. Defendants have habitually turned a blind eye to known or knowable problems in their own supply chain.

8. By doing so, Defendants created conditions in which vast amounts of opioids have flowed freely from their manufacturing facilities to wholesale distributors, fed through doctors and retail pharmacies, and on to abusers and drug dealers, with Defendants filling

suspicious orders from distributors and pharmacies while consciously ignoring "red flags" in the amount and concentration of orders for opioids that require further investigation and resolution before distributing the pills into the regulated controlled-substances supply chain.

9. This kind of behavior by Defendants has allowed massive amounts of opioid pills to be diverted from legitimate channels of distribution into the illicit black market in quantities that have fueled the opioid epidemic in the Cherokee Nation. This is the phenomenon known as "opioid diversion." Acting against their common law and statutory duties, through both illegal marketing and opioid diversion, Defendants have created an environment in which drug diversion can flourish. As a result, unauthorized opioid users in and around the Cherokee Nation have ready access to illicit sources of diverted opioids.

10. For years, Defendants and their agents have had the ability to substantially reduce the death toll and adverse economic consequences of their illegal marketing and diversion of opioids in the Cherokee Nation, but chose to pursue corporate profits instead. Even fines of nearly $700 million in connection with a federal government settlement over OxyContin's "misbranding" in 2007 have failed to curb Purdue and other Defendants' behavior. Defendants have not stopped their continuing pursuit of opioid profits through improper and illegal means.[5]

11. Defendants have caused foreseeable damages to the Cherokee Nation, including the costs of providing: (1) medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (2) counseling and rehabilitation services; (3) treatment of infants born with opioid-related medical conditions; (4) welfare for children whose parents suffer from

[5] Barry Meier, *In Guilty Plea, OxyContin Maker to Pay $600 Million*, N.Y. TIMES, May 10, 2007, *available at* http://www.nytimes.com/2007/05/10/business/11drug-web.html, ("Purdue Pharma and the three executives acknowledged that the company fraudulently marketed OxyContin for six years as a drug that was less prone to abuse, as well as one that also had fewer narcotic side effects.").

opioid-related disability or incapacitation; and (5) law enforcement and public safety relating to the opioid epidemic within the Cherokee Nation. The Cherokee Nation has also suffered substantial damages relating to the lost productivity of Cherokee Nation citizens and businesses.

PARTIES

I. Plaintiff

12. The Cherokee Nation is a federally recognized sovereign Indian nation. It is governed by the Cherokee Nation Constitution and the laws of the Cherokee Nation, and exercises inherent governmental authority within the Cherokee Nation.

13. Cherokee Nation Attorney General Todd Hembree brings this action pursuant to Article VII, Section 13 of the Cherokee Nation Constitution, Title 51, sec. IOI et al. of the Cherokee Nation Code, and in the exercise of his other statutory and common law powers on behalf of the Cherokee Nation in its proprietary capacity and under its *parens patriae* authority in the public interest to protect the health, safety, and welfare of all Cherokee Nation citizens. In particular, Attorney General Hembree brings this action to stop the growing prescription opioid epidemic within the Cherokee Nation and to recover damages and seek other redress for harm caused by Defendants' improper marketing and promotion practices relating to prescription opioids and by Defendants' improper manufacturing, distribution, and reporting practices relating to prescription opioids. Defendants' actions have caused and continue to cause a crisis that threatens the health, safety, and welfare of the citizens of the Cherokee Nation.

II. Corporate Defendants

14. Purdue Pharma L.P. is a limited partnership incorporated in the state of Delaware with its principal place of business in Stamford, Connecticut. Purdue Pharma Inc. is a New York corporation with its principal place of business in Stamford, Connecticut; the Purdue Frederick Company Inc. is a Delaware corporation with its principal place of business in Stamford,

Connecticut; and Purdue Pharma Manufacturing Inc. is a New York corporation with its principal place of business in Stamford, Connecticut (collectively, "Purdue").

15. At all relevant times, Purdue has manufactured, marketed, distributed, sold and continues to manufacture, market, distribute, and sell prescription opioids, including OxyContin, MS Contin, Dilaudid, Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER to distributors, pharmacies, and physicians with locations in the Cherokee Nation. Purdue has engaged in consensual commercial dealings with the Cherokee Nation and its citizens, and has purposefully availed itself of the advantages of conducting business with and within the Cherokee Nation.

16. Actavis plc is a public limited company incorporated in Ireland with a principal place of business in Dublin, Ireland. Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California. It is a wholly owned subsidiary of Allergan plc (f/k/a Actavis, Inc.). Actavis Pharma, Inc. (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.) is a Delaware corporation with its principal place of business in New Jersey. Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey.

17. Allergan plc's corporate history involves several different parent and subsidiary companies operating under different names. Watson Pharmaceuticals had acquired Actavis, Inc. in October 2012. That combined company changed its name to Actavis, Inc. in January 2013, then to Actavis plc in October 2013. Actavis plc acquired Allergan plc in March 2015. The combined company then changed its name to Allergan plc.

18. Each entity in that line of succession is a defendant that Allergan plc owns and uses to market and sell its drugs in the United States. Allergan plc exercises control over those marketing and sales efforts. Profits from the sale of Allergan and Actavis products ultimately

flow to Allergan plc. Allergan plc, Actavis plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are collectively referred to as "Actavis."

19. Actavis markets and sells opioids throughout the United States and within the Tribal Jurisdiction Service Area ("TJSA"). Its most commonly sold branded product is Kadian. It also markets and sells Norco (generic Kadian), as well as generic versions of Duragesic and Opana.

20. Kadian is a Schedule II opioid that contains extended-release morphine sulfate. It was first approved in 1996 for patients hoping to manage severe pain. Actavis acquired the rights to Kadian in 2008 from King Pharmaceuticals, Inc. It began marketing Kadian in 2009.

21. Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals, Inc. is a wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

22. Endo International plc has two principal places of business: one in Dublin, Ireland and the other in Malvern, Pennsylvania.

23. Par Pharmaceutical, Inc. is a Delaware corporation with its principal place of business in Chestnut Ridge, New York. Par Pharmaceutical, Inc. is a wholly owned subsidiary of Par Pharmaceuticals Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc. Defendant Par Pharmaceutical Companies, Inc. is a Delaware corporation with its principal place of business in Chestnut Ridge, New York. Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. (collectively "Par Pharmaceutical") were acquired by Endo International plc in September 2015 and serve as the operating companies of Endo International plc.

24. Endo Health Solutions Inc., Endo Pharmaceuticals, Inc., Endo International plc, and Par Pharmaceutical are collectively referred to as "Endo."

25. Endo develops, markets, and sells prescription drugs nationally and within the TJSA. Those drugs include both brand name and generic opioids including generic oxycodone, oxymorphone, hydromorphone and hydrocodone products and the branded opioids Opana ER, Opana, Percodan, and Percocet.

A. Opana ER is a Schedule II opioid that contains extended-release oxymorphone hydrochloride. It was first approved in 2006 for long-term, constant pain management. The FDA requested in April 2017 that Endo remove Opana ER from the market.

B. Opana is a Schedule II opioid that contains oxymorphone hydrochloride. It was first approved in 2006 for moderate to moderately severe pain management.

C. Percodan is a Schedule II opioid that contains oxycodone hydrochloride and aspirin. It was first approved in 1950, and has been marketed since 2004 for moderate to moderately severe pain management.

D. Percocet is a Schedule I opioid tablet that contains oxycodone hydrochloride and acetaminophen. It was first approved in 1999 for moderate to moderately severe pain management.

26. Defendant Cephalon, Inc. is a corporation organized under the laws of Delaware with its principal place of business in Frazer, Pennsylvania. Teva Pharmaceutical Industries, Ltd. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. Teva Ltd. acquired Cephalon, Inc. in 2011. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a wholly-owned subsidiary of Teva Ltd. Teva USA is a corporation organized

under the laws of Delaware with its principle place of business in Pennsylvania. Teva USA acquired Cephalon, Inc. in October 2011.

27. Teva USA and Cephalon, Inc. work closely with one another to market and sell Cephalon, Inc. products in the United States. Teva USA conducts all sales and marketing activities of Teva Ltd. for Cephalon, Inc. in the United States and has done so since the acquisition of Cephalon, Inc. by Teva Ltd. in October 2011. Teva USA holds out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon, Inc. branded products through its "specialty medicines" division. Teva Ltd.'s financial reports list Cephalon, Inc.'s and Teva USA's sales as its own, and its year-end report for 2012 – the year immediately following the Cephalon, Inc. acquisition – attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of Cephalon's specialty sales." Through interrelated operations like these, Teva Ltd. operates in Oklahoma and the rest of the United States through its subsidiaries Cephalon, Inc. and Teva USA.

28. The United States Food and Drug Administration ("FDA")-approved prescribing information and medication guide – which is distributed with Cephalon, Inc. opioids that are marketed and sold in Oklahoma, including in the 14 counties comprising the TJSA – discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. Teva USA and Cephalon, Inc. are referred to herein as "Cephalon."

29. Cephalon manufactures, promotes, sells, and distributes opioids including generic versions of OxyContin as well as Fentora and Actiq – both Schedule II opioids indicated for the management of breakthrough pain in cancer patients – in the United States and in the TJSA. Fentora is a fentanyl tablet that is placed inside an individual's mouth in a manner similar to chewing tobacco and then allowed to dissolve. Actiq is a fentanyl citrate lozenge similar to a

lollipop. Actiq was granted restricted marketing approval by the FDA in 1998 and was to be promoted only for the "management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."

30. In 2008, Cephalon pleaded guilty to criminal violation of the Federal Food, Drug and Cosmetic Act for the misleading promotion of Actiq and two other drugs for "off-label" uses – *i.e.*, uses not approved by the FDA. Cephalon paid $425 million to resolve the charges.

III. Individual Defendants

31. The individual defendants are current and former directors and officers of Purdue Pharma Inc. In Oklahoma, directors, officers, and employees of corporations are not immune from jurisdiction or liability when they break the law. Instead, every individual is accountable for his or her actions.

32. Richard Sackler, Beverly Sackler, David Sackler, Ilene Sackler Lefcourt, Jonathan Sackler, Kathe Sackler, Mortimer Sackler, and Theresa Sackler controlled Purdue's misconduct. Each of them took a seat on the Board of Directors of Purdue Pharma Inc. Together, they always held the controlling majority of the Board, which gave them full power over both Purdue Pharma Inc. and Purdue Pharma L.P. They directed deceptive sales and marketing practices deep within Purdue, sending hundreds of orders to executives and line employees. From the money that Purdue collected selling opioids, they paid themselves and their family billions of dollars.

33. Beverly Sackler, Jonathan Sackler, and Kathe Sackler, reside in Connecticut. David Sackler, Ilene Sackler Lefcourt, and Mortimer Sackler reside in New York. Richard Sackler resides in Florida. Theresa Sackler resides in the United Kingdom.

34. The Court has jurisdiction over all the individual and corporate defendants for the reasons set forth below.

JURISDICTION AND VENUE

35. This Court has jurisdiction over Defendants because Defendants conduct business in and throughout Oklahoma, including in Sequoyah County and on land that constitutes "Indian country" under 18 U.S.C. § 1151 within the Cherokee Nation, and have deliberately engaged in significant acts and omissions within Oklahoma, Sequoyah County, and Indian country that have injured the Cherokee Nation's citizens. Defendants purposefully directed their activities at Oklahoma and its citizens and the Cherokee Nation and its citizens, and the claims arise out of those activities.

36. In addition, this Court has personal jurisdiction over Defendants, each of which has substantial contacts and business dealings throughout the Cherokee Nation and Oklahoma by virtue of their marketing, sales, manufacturing, and distribution of prescription opioids within the Cherokee Nation territorial and political jurisdiction.

37. The individual defendants are current and former directors and officers of Purdue Pharma Inc. In Oklahoma, directors, officers, and employees of corporations are not immune from jurisdiction or liability when they break the law. Instead, each individual is accountable for his or her actions.

38. Richard Sackler, Beverly Sackler, David Sackler, Ilene Sackler Lefcourt, Jonathan Sackler, Kathe Sackler, Mortimer Sackler, and Theresa Sackler voted for and/or ordered sales reps to go door-to-door, making thousands of visits to doctors in Oklahoma and Indian County to implement the deceptive scheme described in this Complaint.

39. Richard Sackler, Beverly Sackler, David Sackler, Ilene Sackler Lefcourt, Jonathan Sackler, Kathe Sackler, Mortimer Sackler, and Theresa Sackler directed payments to Oklahoma doctors such as payments in exchange for the doctors' promotion of Purdue drugs.

40. Richard Sackler, Beverly Sackler, David Sackler, Ilene Sackler Lefcourt, Jonathan Sackler, Kathe Sackler, Mortimer Sackler, and Theresa Sackler directed the dissemination of tens of thousands of copies of unfair or deceptive marketing materials to health care providers throughout Oklahoma to get more and more patients on Purdue's drugs for longer and longer periods of time at higher and higher doses. Although they did not lick the stamps themselves, these individuals directed and/or managed a chain-of-command that caused these mailings in Oklahoma and Indian Country because they meant increased sales and profits for the individual defendants and their executives.

41. Likewise, Richard Sackler, Beverly Sackler, David Sackler, Ilene Sackler Lefcourt, Jonathan Sackler, Kathe Sackler, Mortimer Sackler, and Theresa Sackler directed sales reps to go door-to-door, making thousands of visits to doctors in Oklahoma and Indian Country. Although they did not knock on the doors to clinics and family practices themselves, these individuals voted for and/or ordered sales reps to deceptively promote Purdue's dangerous drugs in person, as a central facet of their deceptive marketing scheme that killed hundreds of people in Oklahoma and Indian Country.

42. This action arises from Richard Sackler, Beverly Sackler, David Sackler, Ilene Sackler Lefcourt, Jonathan Sackler, Kathe Sackler, Mortimer Sackler, and Theresa Sackler causing tortious injury in Oklahoma and Indian Country. As described in this Complaint, each individual defendant voted for, directed, and/or managed Purdue's misconduct, which has killed

hundreds of people in Oklahoma and from which they directly profited. Each individual defendant derived substantial revenue from goods used or consumed in Oklahoma.

43. The directors paid themselves handsomely for their positions on Purdue's Board. Each director defendant was on the board for at least five years (and in many cases for twenty years). In exchange for sitting on the board, Purdue paid each director defendant more than $600,000.

44. The Cherokee Nation has inherent sovereignty over unlawful conduct by non-Indians on lands that constitute Indian country within the Cherokee Nation, including on land owned by or held in trust by the Cherokee Nation. Defendants have engaged in activities and conduct that take place on, or have direct impact on, land that constitutes Indian country within the Cherokee Nation.

45. The Cherokee Nation brings this action against the non-tribal-member Defendants based upon consensual relationships with members of the Cherokee Nation and as the Defendants' wrongful conduct constitutes and poses a significant ongoing threat to the health, welfare, political integrity, and economic security of the Cherokee Nation and its members.

I. Causes of Action Arising in the Tribal Jurisdictional Service Area ("TJSA")

46. The TJSA is recognized in federal, state, and tribal law as the territorial area of the Cherokee Nation established by prior treaties between the United States and the Cherokee Nation.

47. This TJSA encompasses the whole or part of 14 Oklahoma counties – Adair, Cherokee, Craig, Delaware, Mayes, McIntosh, Muskogee, Nowata, Ottawa, Rogers, Sequoyah, Tulsa, Wagoner, and Washington – all in northeastern Oklahoma, as shown on the map attached

as **Exhibit A**, entitled "Tribal Jurisdictions in Oklahoma" prepared by the State of Oklahoma Department of Transportation.[6]

48. The Cherokee Nation has approximately 355,000 citizens. Of these, approximately 177,000 reside within the TJSA. Cherokee Nation citizens comprise a significant percentage of the population in these counties.

49. The TJSA is widely recognized in federal law as territory in which the Cherokee Nation has governmental authority to administer a variety of federal programs and to exercise sovereign rights.

50. For example, the Cherokee Nation has the authority under the Indian Self-Determination Act to enter into annual self-governance compacts and funding agreements to run Bureau of Indian Affairs' programs located throughout the TJSA where such programs are of "special . . . significance" to the Nation. *See* 25 C.F.R. §§ 1000.125-.126; 25 U.S.C. §§ 5384-85. The 2006 Compact between Indian Health Service and the Cherokee Nation, for instance, in a section titled "Territorial Jurisdiction of the Cherokee Nation," describes "the boundaries of the Cherokee Nation territory" as the areas set by the patents of 1838 and 1846, as modified, and further describes the Cherokee Nation "service area" under the Compact as "within all or part of a fourteen county area located in the Claremore and Tahlequah Service Units of the Oklahoma City Area Indian Health Service." *See* 2006 Compact § 1.3.

51. The federal government has authorized the Cherokee Nation to receive federal funding to support the exercise of "tribal control in all matters relating to the education of Indian children" within the TJSA. 25 U.S.C. § 2020(d)(1).

[6] Also available at http://www.okladot.state.ok.us/maps/tribal/map_tribal_odot-div.pdf.

52. Federal law authorizes the Nation to implement federal grants within the TJSA where such grants further the development and support of tribal courts exercising jurisdiction within the jurisdictional territory. 25 U.S.C. §§ 3653(3), 3681.

53. Federal law also recognizes Cherokee Nation authority in the TJSA for multiple other purposes. *See, e.g.*, 25 U.S.C. § 4302(4)(B)(i) (the Cherokee Nation's "jurisdictional areas" are equivalent to a "reservation" for purposes of receiving grants under the Native American Business Development, Trade Promotion, and Tourism Act of 2000); *id.* §§ 3201(b)(4), 3202(9), 3208(a) (the Cherokee Nation has authority to implement federal grants for treatment programs for victims of child sexual abuse within the Cherokee Nation jurisdictional area); *id.* §§ 3102, 3103(12), 3104(b)(2), (4) (recognizing the Cherokee Nation's interest in use of national forest lands and proceeds from sale of products of national forests within the Cherokee Nation jurisdictional area); *id.* § 3115 (providing that the Secretary of Interior can enter into cooperative agreements with tribes for the management of national forest lands in their jurisdictional areas); 40 U.S.C. § 523(b)(2) (recognizing the Cherokee Nation's jurisdictional area for purposes of transferring excess federal government owned lands into tribal trust status); *see also* 25 C.F.R. § 151.2(f) (treating the TJSA as its "reservation" for purposes of acquiring trust land for the Cherokee Nation).

54. For instance, an extensive "Law Enforcement Agreement Between and Among the Cherokee Nation, the United States of America, the State of Oklahoma, and Its Political Subdivisions, the Various Boards of County Commissioners, and Various Law Enforcement Agencies," dated July 8, 1992, creates an intergovernmental Cherokee Nation Law Enforcement Compact that establishes the terms for cross-deputization of federal, state, and tribal law enforcement personnel "within the boundaries of the Cherokee Nation." Law Enforc. Agmt. at

1. For purposes of the agreement, the "Cherokee Nation's boundaries" are depicted on a map attached to the Compact as the TJSA.

55. The State of Oklahoma and the Cherokee Nation have also entered into a "Motor Vehicle Licensing Compact Between the Cherokee Nation and the State of Oklahoma for Lands Located Within the Compact Jurisdictional Area of the Cherokee Nation," dated August 16, 2013. That Compact allows the Nation to license motor vehicles owned by citizens of the Cherokee Nation pursuant to Cherokee Nation Law within the "Compact Jurisdictional Area of the Cherokee Nation." It also defines the boundaries of the "Compact Jurisdictional Area of the Cherokee Nation" by reference to a map attached to the Compact, depicting the same TJSA referenced in paragraph 47 above.

56. Similarly, the TJSA is recognized by the Cherokee Nation as territory in which the Cherokee Nation has governmental authority to administer tribal programs and to exercise sovereign rights.

57. The Constitution of the Cherokee Nation defines the boundaries of "the Cherokee Nation territory" as "those described by the patents of 1838 and 1846 diminished only by the Treaty of July 19, 1866, and the Act of March 3, 1893." Cherokee Const., Art. II. That area is co-extensive with the TJSA described above.

58. The TJSA is "Indian country" under 18 U.S.C. § 1151(a) because it is an undiminished reservation which was established by the Treaty of New Echota, 7 Stat. 478 (Dec. 29, 1835), and whose final boundaries were established by the 1866 Treaty of Washington, 14 Stat. 799 (July 19, 1866), an area that is coextensive with the TJSA.

59. The Code of the Cherokee Nation asserts the Cherokee Nation's jurisdiction over activity within the TJSA for multiple purposes. For instance, Title 27, Ch. 1 § 104 of the

Cherokee Nation Code states that "[f]or purpose[s] of enforcing the provisions of the Cherokee Nation Environmental Act, the Cherokee Nation shall have jurisdiction in the territorial boundaries of the Cherokee Nation as defined in the Patent of 1838 . . . ." *See also* Title 33, Ch. 1 § 3(5) (defining authority of Cherokee Nation Housing Authority); Title 68, Ch. 9 §§ 102, 103(4) (imposing tax on waste "generated outside the original territorial jurisdiction of the Cherokee Nation," which is described as "all land within the fourteen (14) county area of northeastern Oklahoma as defined by the treaties of 1828, 1833 and 1835 and the Patent of 1838 . . . ."); Title 68, § 1353 (imposing motor vehicle licensing requirement on vehicles "within the reservation boundaries of Cherokee Nation").

60. Defendants have substantial contacts and business relationships with the Cherokee Nation, the citizens of the Cherokee Nation, employees of the Cherokee Nation, and/or Cherokee Nation businesses. Defendants have purposefully availed themselves of business opportunities within the TJSA. This includes activities in communities of high Cherokee Nation citizen population density that have a unique and undeniable tribal character.

II. Causes of Action Based on Consensual Relationships

61. In addition, the Cherokee Nation has jurisdiction over causes of action arising from the conduct of non-Indians within the TJSA when that conduct is (1) based on consensual relationships between the Cherokee Nation and non-Indians; and (2) threatens or has some direct effect on the political integrity, the economic security, or the health or welfare of the Cherokee Nation.

62. Defendants' manufacturing and distribution activities, marketing activities, and conduct, which have predominantly been actions undertaken by non-Indians within the TJSA, such as distributing opioids intended for pharmacies and patients located in the TJSA, directing opioid marketing materials into the TJSA, and conducting sales activities in the TJSA, have

threatened and continue to threaten the economic security and the health and welfare of the Cherokee Nation through their promotion of the opioid epidemic.

III. Causes of Action Arising Out of Threats to the Cherokee Nation

63. Finally, the Cherokee Nation has jurisdiction over causes of action arising from conduct that threatens or has some direct effect on the political integrity, the economic security, or the health and welfare of the Cherokee Nation.

64. Defendants' conduct has caused and is causing a health crisis in the Cherokee Nation that threatens the health, welfare, economic security, and political integrity of the Cherokee Nation and all of its citizens. As a result of Defendants' actions, the citizens of the Cherokee Nation have become addicted to prescription opioid drugs, causing serious injury or death, requiring rehabilitation and medical treatment for substance use disorder, causing children to be born addicted to prescription opioids and other controlled substances, and causing short- and long-term emotional and physical damage that requires treatment, long-term care, and in some instances foster care or adoption. The financial impact on the Cherokee Nation has been enormous.

65. The negative impacts on the next generation of Cherokee Nation citizens caused by Defendants' conduct threaten the continuation of Cherokee Nation culture, identity, and effective self-government. These impacts are so severe, cumulatively, that Defendants' conduct threatens to destroy the Cherokee Nation.

FACTS COMMON TO ALL CLAIMS

I. The Prescription Opioid Crisis

66. Opioid literally means "opium-like," and the term includes all drugs derived in whole or in part from the opium poppy. Opioid drugs are also commonly referred to as narcotics.

67. The FDA's website describes prescription opioids as "powerful pain-reducing medications that include prescription oxycodone, hydrocodone, and morphine, among others, and have both benefits as well as potentially serious risks. These medications can help manage pain when prescribed for the right conditions and when used properly in light of their inherent risks. But when misused or abused, they can cause addiction, overdose, and death."[7]

68. Prescription opioids are not new, and have long been studied by the scientific and regulatory communities. For example, oxycodone, the active ingredient in Purdue's OxyContin, has been in clinical use since 1917.[8] Another common prescription opioid, hydrocodone, has been in clinical use in Europe since 1924 and was originally approved by the FDA in 1943.[9]

69. Through the 1980s, opioid pain medications were primarily prescribed to treat (i) acute pain, typically defined as pain that persists beyond the normal time of healing, or pain that lasts for less than three months,[10] and (ii) cancer pain.[11] By contrast, opioid pain medications were not commonly prescribed to treat "chronic pain," or non-cancer related pain that lasts for more than three months.

70. Physicians were reluctant to prescribe opioid drugs for chronic pain out of concern that this would lead to patient abuse and addiction. The dangers of opioid addiction were well known among physicians. In his book on cancer pain written approximately 60 years ago, Dr. Warren Cole, a surgeon, noted: "We must appreciate that severe constant pain will

[7] FDA, *Opioid Medications*, https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm337066.htm (last visited May 24, 2017).
[8] Eija Kalso, *Oxycodone*, 29 J. PAIN AND SYMPTOM MGMT. S47, S47 (May 2005).
[9] Drug Products Containing Hydrocodone; Enforcement Action Dates, 72 Fed. Reg. 55780, 55781 (Oct. 1, 2007).
[10] Task Force on Taxonomy of the Int'l Ass'n for the Study of Pain, CLASSIFICATION OF CHRONIC PAIN, xi (Harold Merskey & Nikolai Bogduk, eds.) (1994).
[11] U.S. Food & Drug Admin., Timeline of Selected FDA Activities and Significant Events Addressing Opioid Misuse and Abuse 1911-1999, https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm338566.htm (last visited Mar. 5, 2018).

destroy the morale of the sturdiest individual. . . . But . . . we are often loathe to give liberal amounts of narcotics because the drug addiction itself may become a hideous spectacle."[12]

II. Defendants' Marketing Machine

71. From roughly the mid-1990s to the present, Defendants aggressively marketed prescription opioids and misleadingly represented those drugs as having little to no risk of addiction. Defendants ignored the available scientific evidence showing that opioids were addictive, even when used for long-term treatment of chronic pain. Instead, they enlisted physicians and sham medical organizations to press their preferred message – that opioids were safe in nearly any treatment plan. That strategy gave a sense of legitimacy to Defendants' misrepresentations, allowing them to reap ever-higher profits from the sale of dangerous, highly addictive drugs.

72. Though all Defendants engaged in deceptive and unsupported marketing, Purdue led the way, having discovered early on that money was to be made not in the creation of pharmaceuticals but in their marketing. As the Medical Advertising Hall of Fame later put it, Purdue made billions from "bringing the full power of advertising and promotion" to the business of selling opioids.[13]

73. In 1952, three brothers – Mortimer, Raymond, and Arthur Sackler – purchased what was then a small, 60-year-old drug company, Purdue Frederick. Purdue Frederick sold a variety of medical products, such as tonics, laxatives, and antiseptics.[14]

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[12] Marcia L. Meldrum, *The Ongoing Opioid Prescription Epidemic: Historical Context*, 106 AM. J. PUB. HEALTH 1365 (Aug. 2016) (*quoting* Int'l Assn for the Study of Pain, *Opioids and Pain Relief: A Historical Perspective* 196, 198, 200-08 (Maria L. Meldrum ed., 2002)).

[13] Patrick Radden Keefe, *Empire of Pain*, The New Yorker, Oct. 30, 2017, at 36.

[14] Katherine Eban, *OxyContin: Purdue Pharma's painful medicine*, FORTUNE (Nov. 21, 2011), *available at* http://katherineeban.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine-fortune/ (last visited Mar. 9, 2018).

74. Arthur Sackler was already known at the time as an expert in pharmaceutical marketing. He pioneered the usage of radio and television advertising for pharmaceutical marketing as far back as the 1950s. And he has been credited with the now-common pharmaceutical industry sales approach of marketing drugs directly to physicians by plying them with highly compensated speaking engagements, expensive dinners, and trips to conferences, all with the intent to entice doctors to prescribe more of the pharmaceutical company's drugs.[15]

75. Arthur Sackler's efforts in pharmaceutical marketing techniques were wildly successful. Arthur was responsible for turning Valium, an anti-anxiety medication, into the first-ever $100 million drug. He did so largely by expanding the types of uses for the drug, and by encouraging doctors to prescribe Valium for these newly expanded uses, a technique that would later be used to create the enormous market for opioid drugs.

76. Arthur's success in pharmaceutical marketing ultimately led to him being one of the first individuals inducted into the Medical Advertising Hall of Fame in 1997, with the recognition that he "helped shape pharmaceutical promotion as we know it today . . . as well as established the role of communications and promotional programs in pharmaceutical marketing."[16]

77. Witnessing their brother's marketing successes, Mortimer and Raymond Sackler quickly realized that Purdue Frederick's future was in drug marketing, not new drug development. Beginning in 1984, using the Arthur Sackler playbook, Purdue Frederick took an existing generic opioid drug used to treat cancer pain – morphine sulfate – formulated it into a time-release dosage, and began selling it as the branded drug MS Contin.

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[15] *Id.*

[16] *Id.*; Medical Advertising Hall of Fame Inductees, Arthur M. Sackler, *available at* https://www.mahf.com/mahf-inductees/ (last visited June 6, 2017).

78. Over roughly the next ten years, Purdue positioned itself as a pain management "educator" in its marketing of MS Contin, earning a position of trust and respect among cancer and pain specialist physicians.[17] That marketing approach was handsomely rewarded, as sales of MS Contin approached $500 million over those ten years. So successful were its efforts with MS Contin that Purdue Frederick decided to spin off its pain treatment business into its own company, Purdue Pharma.[18]

79. To support the growth of MS Contin and the expanded use of opioid drugs, Purdue was one of several pharmaceutical companies – others included Defendants Cephalon and Endo – to sponsor physicians who were willing to challenge the long-held views that opioids were unsafe for the general treatment of chronic pain. Chief among these researchers was Dr. Russell Portenoy, a pain specialist and researcher at Memorial Sloan Kettering Cancer Center in New York. Dr. Portenoy received research support, consulting fees, and honoraria from Cephalon, Endo, and Purdue (among others), and was a paid consultant to Cephalon and Purdue. In 1986, Dr. Portenoy published a report with Dr. Kathleen Foley, the head of Sloan Kettering's pain treatment center, titled "Chronic Use of Opioid Analgesics in Non-Malignant Pain."[19]

80. Drs. Portenoy and Foley's report was small, covering only 38 patients. It concluded that "[f]ew substantial gains in employment or social function could be attributed to the institution of opioid therapy," and "that opioid maintenance therapy can be a safe, salutary and more humane alternative to the options of surgery or no treatment in those patients with intractable non-malignant pain and no history of drug abuse."[20]

[17] Barry Meier, PAIN KILLER: A "WONDER" DRUG'S TRAIN OF ADDICTION AND DEATH 96-97 (2003).
[18] Eban, *supra* note 14.
[19] Meier, *supra* note 17 at 63-65.
[20] Russel Portenoy & Kathleen Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report of 38 Cases*, 25 PAIN 171, 171 (1986).

81. While the size of the study in the Portenoy report was small, the fact that it came from a highly respected institution and was co-authored with Dr. Foley – considered an expert in the field of pain treatment – meant that it had an outsized effect in the market. Dr. Portenoy was invited to lecture on pain relief at talks and continuing education programs for physicians across the country – talks and programs often sponsored directly by drug companies, including Purdue, Cephalon, and Endo, or indirectly by foundations or organizations supported by the pharmaceutical industry.[21]

82. Buoyed by its initial successes with MS Contin, Purdue realized that it needed to expand the pain market beyond cancer patients to continue growing its pain treatment drug sales. It did so with its revolutionary marketing of OxyContin.

83. As noted by Fortune magazine, "Purdue's breakthrough [was] one of marketing rather than medicine."[22] It consisted of taking an old generic opioid drug, oxycodone, that was more powerful than morphine, formulating it into a time-release capsule, and extensively marketing this new product – OxyContin – for a broad range of chronic, non-cancer pain. That marketing effort was bolstered by doctors, such as Dr. Portenoy, and the extremely limited amount of research that purported to show that opioids were safe to use for the treatment of chronic pain.

84. In fact, and in contrast to Dr. Portenoy's research conclusions, the FDA noted in 1995 that OxyContin had no significant advantages over the then-conventional approach of opioid treatments other than the frequency of dosing.[23]

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[21] Meier, *supra* note 17 at 64-65.
[22] Eban, *supra* note 14.
[23] Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 AM. J. PUB. HEALTH 221 (Feb. 2009).

85. Nonetheless, the FDA approved Purdue's new drug application for OxyContin in late 1995, and Purdue introduced OxyContin to the market in early 1996.

86. Once introduced to the market, Purdue put its marketing and promotion plan for OxyContin into high gear. From 1996 to 2001, Purdue conducted more than 40 pain management and speaker training sessions at Florida, Arizona, and California resorts to recruit and train physicians, nurses, and pharmacists as speakers on behalf of Purdue. Purdue trained more than 5,000 people at these all-expense-paid events.[24] Other Defendants used that tactic, too. Actavis, for instance, set a goal to train 100 new Kadian speakers in 2008 alone, with a plan to set up "power lunch teleconferences" connecting speakers to up to 500 participating sites nationwide. The same year, Endo spent nearly $4 million to promote almost 1,000 speaker programs across the country; it later contracted with a medical communications firm to operate its speakers' bureau, planning hundreds of "peer-to-peer promotional programs" for Opana ER in the second half of 2011, including dinners, lunches, and breakfasts.

87. In addition, the DEA has estimated that Purdue funded over 20,000 opioid pain-related educational programs between 1996 and July 2002 through direct sponsorship or financial grants.[25]

88. Research studies have shown that these types of events and symposia influence the attending physicians' prescribing habits, notwithstanding their beliefs that being treated to such all-expenses-paid junkets do not alter their drug prescribing patterns.[26]

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[24] *Id.*

[25] U.S. Gen. Acct. Office, GAO-04-110, *Prescription Drugs–OxyContin Abuse and Diversion and Efforts to Address the Problem* 23 (Dec. 2003), https://www.fda.gov/ohrms/dockets/ac/08/briefing/2008-4395b1-01-FDA.pdf (retrieved June 6, 2017).

[26] Van Zee, *supra* note 23 at 221-22.

89. Beginning in 1996, Purdue had approximately 300 sales representatives promoting OxyContin; by 2000, it had more than doubled its internal sales force to 671 and had partnered with another pharmaceutical company to further expand the total sales force to nearly 1,000.[27]

90. By more than doubling its sales force, Purdue greatly expanded the number of physicians to which OxyContin was being marketed.[28] Each sales representative was generally assigned a territory and was responsible for assembling a list of approximately 100 to 140 actual or potential opioid-prescribing physicians to call upon. By 1996, Purdue's sales team was calling on between 33,000 to 44,500 physicians. By 2000, that number had grown to between 70,500 to 94,000 physicians.[29]

91. This vast sales team was motivated to push OxyContin and increase sales. Purdue offered significant bonuses to sales representatives that increased sales of OxyContin in their territories. In 2001, the average annual salary of a Purdue sales representative was $55,000, but the average bonus for sales representatives that year was $71,500; the highest bonus was nearly $240,000. Purdue paid nearly $40 million in sales bonuses in that year alone.

92. But lavishly compensating its sales representatives and treating physicians to dinners and training junkets was only a part of the marketing strategy. Purdue also widely distributed OxyContin-branded promotional items to physicians and pharmacists, such as plush

[27] U.S. Gen. Acct. Office, *supra* note 25 at 19.
[28] Purdue's recent face-saving efforts to diminish its sales staff and to stop marketing opioid drugs to physicians are long overdue. These actions acknowledge what Purdue has long known to be true – that opioids for the treatment of long-term pain are prone to abuse – but do not alter Purdue's earlier efforts which directed the vast majority of its resources to market those very drugs it now seeks to distance itself from.
[28] U.S. Gen. Acct. Office, *supra* note 23 at 19-20.
[29] *Id.*

toys and music compact discs – something the DEA later noted was "unprecedented" for a Schedule II narcotic drug.[30]

93. Purdue stopped at nothing to push its product. For example, Purdue sales representatives distributed patient starter coupons for free 7- to 30-day prescriptions of OxyContin. By 2001, approximately 34,000 of these coupons had been redeemed.[31]

94. All told, the DEA estimated that Purdue spent approximately 6 to 12 times more on OxyContin promotional efforts during the first six years that it was on the market than a competitor had spent on similar promotional efforts in total.[32]

95. These marketing efforts paid dividends for Purdue. While sales of OxyContin were only about $45 million in 1996, by 2002, sales had increased to over $1.5 billion, with over 7 million OxyContin prescriptions being filled per year.[33] Notably, many of those prescriptions were being written not by pain management specialists, but instead by primary care physicians who were generally not as extensively trained on pain management or opioid addiction issues.[34] In a January 2002 meeting involving a special advisory panel to the FDA, even industry champion Dr. Portenoy acknowledged this concern, stating: "Generalists are adopting the [opioid] therapy without adequate knowledge of pain management principles."[35]

96. Purdue knew this to be the case, as it was a key component of its marketing strategy. As one study of OxyContin's history stated: "One of the critical foundations of Purdue's marketing plan for OxyContin was to target the physicians who were the highest prescribers for opioids across the country. The resulting database would help identify physicians

[30] Van Zee, *supra* note 23 at 222.
[31] *Id.*
[32] U.S. Gen. Acct. Office, *supra* note 25 at 21.
[33] *Id.* at 31.
[34] By 2003, nearly half of all physicians prescribing OxyContin were primary care physicians. Van Zee, *supra* note 23 at 222.
[35] Meier, *supra* note 17 at 184.

with large numbers of chronic pain patients. Unfortunately, this same database would also identify which physicians were simply the most frequent prescribers of opioids and, in some cases, the least discriminate prescribers."[36]

97. This database has given Purdue extensive knowledge of where and how its drugs are being used across the country, including in the TJSA. As noted in a medical journal article discussing the history of OxyContin's marketing, "[o]ne of the cornerstones of Purdue's marketing plan was the use of sophisticated marketing data to influence physicians' prescribing. Drug companies compile prescriber profiles on individual physicians – detailing the prescribing patterns of physicians nationwide – in an effort to influence doctors' prescribing habits. Through these profiles, a drug company can identify the highest and lowest prescribers of particular drugs in a single zip code, county, state, or the entire country."[37]

98. Purdue relied on this data to drive opioid sales even higher. By 2010, it is estimated that OxyContin sales exceeded $3 billion, an amount that accounted for a third of ***all*** sales revenue from pain relief medication in the industry that year.

99. More recently, as Purdue looked to expand the marketplace for OxyContin and its other opioid products worldwide, it began exporting its aggressive and deceptive practices to international markets. In 2016, the *L.A. Times* reported that Purdue is now pushing its message of opioids for the broad treatment of chronic pain in Spain using naked celebrities to advocate for individuals to seek out opioids as a remedy for the aches and pains of life.[38]

100. Purdue's history and its billions of dollars in profits were never attributable to its pharmaceutical innovation capabilities, but instead were the product of its vast resources in terms

[36] Van Zee, *supra* note 23 at 222.
[37] *Id.*
[38] Harriet Ryan, Lisa Girion, & Scott Glover, *OxyContin Goes Global–'We're only just getting started'* L.A. TIMES (Dec. 18, 2016), *available at* http://www.latimes.com/projects/la-me-oxycontin-part3/.

of sales force, marketing dollars, training events, dinners, and sponsorships, all directed to creating an unstoppable marketing machine for a potent and dangerous class of drugs. And, once the marketing machine created the widespread appetite for opioids, Purdue has continued to supply epidemic-inducing quantities of prescription opioids in and around the Cherokee Nation with the actual or constructive knowledge that many of the opioids were being diverted and ultimately being consumed by Cherokee Nation citizens for non-medical purposes.

101. While the playbook for marketing dangerous opioids began with Purdue, it did not end there. Having witnessed the billions of dollars in profits attributable to widespread marketing, other opioid manufacturers, including Defendants, followed suit. Defendants poured money into training events, publications, and sponsorships, to convince physicians that opioids were safe even when prescribed beyond their intended use. Despite a recent outpouring of data highlighting the addictive nature of opioids when used in certain instances, Defendants have continued to supply prescription opioids in and around Oklahoma knowing that many opioids are being diverted or consumed for non-medical purposes.

III. Defendants' Deceptive Marketing

102. Defendants' vast opioid marketing machine has not just been aggressive. It has also, since the beginning, been deceptive and misleading. Indeed, it has systematically and repeatedly minimized or misstated the risks of addiction, abuse, and withdrawal when opioids are used for the general treatment of chronic pain.[39]

103. During most of the twentieth century, the widely held perception among physicians was that the long-term use of opioid drugs to treat chronic pain was not a reasonable

[39] Van Zee, *supra* note 23 at 223.

approach to treatment due to the risks of addiction, increased disability, and lack of efficacy of the drugs when used over a long period of time by a patient.[40]

104. Yet despite this general understanding among the medical community, Defendants chose consistently to misrepresent the dangers of opioid addiction. For example, Defendants repeatedly cited an unreviewed claim in a 1980 letter to the editor in the New England Journal of Medicine that purported to find opioid addiction in only 4 of 11,882 hospitalized patients who had no previous history of addiction.[41]

105. Recently, the President's Commission on Combating Drug Addiction and the Opioid Crisis recognized the detrimental role the 1980 letter played.[42] In a section of the Commission's Report titled "Contributors to the Current Crisis," the Commission noted that the 1980 letter was an "early catalyst" to unsubstantiated claims that misrepresented the dangers of addiction. The Commission continued, stating that the 1980 letter "offered no information on opioid dose, number of doses, the duration of opioid treatment, whether opioids were consumed after hospital discharge, or long-term follow-up, nor a description of criteria used to designate opioid addiction." Despite its flawed conclusion and complete lack of support, Defendants have cited this 1980 letter to support their marketing campaign.

106. Defendants also repeatedly cited a 1982 study of burn victims that found no addiction issues for patients that were treated with opioids for pain management.[43] But crucially,

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[40] Andrew Rosenblum, et al., *Opioids and the Treatment of Chronic Pain: Controversies, Current Status, and Future Directions*, 16 EXPERIMENTAL AND CLINICAL PSYCHOPHARMACOLOGY 405, 405 (2008), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2711509/#R17.

[41] Jane Porter & Jick Hershel, M.D., *Addiction Rare in Patients Treated with Narcotics*, 302 NEW ENG. J. MED. 123, 123 (1980).

[42] *The President's Commission on Combating Drug Addiction and the Opioid Crisis* at 20 (Nov. 1, 2017), https://www.whitehouse.gov/sites/whitehouse.gov/ files/images/Final_Report_Draft_11-1-2017.pdf.

[43] Samuel Perry & George Heidrich, *Management of Pain During Debridement: A Survey of U.S. Burn Units*, 13 PAIN 267, 267-80 (1982).

these studies did not address the core question and focus of Defendants' marketing efforts, which was the safety of opioids when used for ***long-term*** chronic pain management.

107. Defendants ensured their salespeople knew these messages intended to downplay any potential for abuse or addiction. Each new salesperson hired by Purdue, for example, received four days of training on MS Contin and OxyContin. As part of the training, Purdue instructed the salespeople that the addiction risk posed by the narcotic pain drugs was "less than one percent."[44] This is not supported by scientific evidence. Similarly, in one 2010 sales training, Actavis employees were told to instruct prescribers that "most chronic benign pain patients do have markedly improved ability to function when maintained on chronic opioid therapy." Actavis later told Kadian sales representatives that the drug was less addictive than other prescription opioids. Neither of those assertions is supported by scientific evidence.

108. In place of real science, Defendants instructed their sales representatives to give prescribers the erroneous and misleading impression that opioids were safer than alternative pain-management treatment options. Actavis sales representatives, for instance, were coached to tell physicians that non-prescription NSAIDs "can have toxic effects on the kidney" and "should only be taken short term." But opioids, they were told, showed no significant dangerous side effects, including risks of addiction: Actavis trainings repeatedly pressed the false assertion that "there is no evidence that simply taking opioids for a period of time will cause substance abuse or addiction." Endo did the same thing, distributing a presentation to physicians titled "Case Challenges in Pain Management: Opioid Therapy for Chronic Pain." That presentation pointed to one patient whose long-term NSAID use had led to "a massive upper gastrointestinal bleed." Endo recommended that physicians avoid that result by prescribing opioids instead.

[44] Meier, *supra* note 17 at 99.

109. Defendants also represented to doctors in its marketing materials that "addiction to opioids legitimately used in the management of pain is very rare" and, in a Purdue-sponsored training session for doctors, called addiction to opioids "exquisitely rare." [45] This, too, is not supported by scientific evidence.

110. Some Defendants courted prescribers through "detailers" – sales representatives who visited the same doctor's offices repeatedly. By establishing close relationships with physicians, those sales representatives were able to disseminate their misrepresentations in targeted, one-on-one settings that allowed them to differentiate their opioids and address prescribers' concerns about prescribing opioids for chronic pain. Representatives were trained on techniques to build these relationships, with Actavis even rolling out an "Own the Nurse" kit as a "door opener" to time with doctors. Endo had a similarly aggressive detailing program. In the first quarter of 2010 alone, sales representatives made nearly 72,000 visits to prescribers to sell Opana ER. Between 2007 and 2013, Endo spent between $3 million and $10 million each quarter to promote opioids through its sales force.

111. Defendants targeted physicians who were likely to prescribe opioids for chronic pain. With time, that meant targeting primary care physicians and general practitioners, rather than only specialists. Endo, for example, released a 2007 internal report that outlined its aim of increasing "Opana ER business from the [primary-care physician] community" by more than 45% that year. Cephalon had a similar goal. Using the slogan "pain is pain," Cephalon instructed Actiq sales representatives to focus on general practitioners as well as oncologists and to push physicians to prescribe the drug for off-label uses. (Cephalon eventually began training its sales force to disregard the restrictions of certain FDA-approved labels and tying sales

[45] *Id.* at 190.

bonuses to representatives' ability to obtain off-label prescriptions.) Likewise, Actavis rolled out a plan in 2008 to move beyond "Kadian loyalists" to an "expanded audience" of "low morphine writers."

112. Defendants spent hundreds of millions on advertising because they saw that it worked. Numerous studies have shown that direct marketing influences physicians' off-label prescribing habits.[46] And face-to-face marketing often has the biggest influence on a physician's decision to prescribe. As Defendants' marketing campaigns grew more sophisticated, more physicians began to write prescriptions for opioids – and those that had already been prescribing them did so at an even higher rate. Through it all, Defendants' profits climbed steadily.

113. Before long, Defendants were put on notice that they were improperly marketing a very dangerous opioid drug. By March 2000, Purdue employees had received reports of OxyContin abuse and diversion in several different communities.[47] And on May 11, 2000, Purdue received a letter from the FDA warning Purdue to cease the use of an advertisement for OxyContin that recommended using the drug to treat arthritis patients without first trying milder drugs.

114. A year later, in July 2001, the DEA ordered Purdue to include a "black box warning," the strongest type of warning for an FDA-approved drug, on all OxyContin labels to call attention to the potential for misuse, abuse, and diversion of the drug. According to the DEA, 117 people across 31 states had died from OxyContin abuse as of December 2001.

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[46] *See, e.g.*, Puneet Manchanda and Pradeep K. Chintagunta, *Responsiveness of Physician Prescription Behavior to Salesforce Effort: An Individual Level Analysis*, 15 (2-3) Mktg. Letters 129 (2004); Ian Larkin, *Restrictions on Pharmaceutical Detailing Reduced Off-Label prescribing of Antidepressants and Antipsychotics in Children*, 33(6) Health Affairs 1014 (2014).

[47] Plea Agreement, Attachment F ¶41, *United States v. The Purdue Frederick, Inc.*, No. 07-cr-00029 (W.D. Va, May 10, 2007).

115. In 2008, Cephalon pleaded guilty to criminal violation of the Federal Food, Drug and Cosmetic Act for the misleading promotion of Actiq and two other drugs for "off-label" uses *i.e.*, uses not approved by the FDA. From 2001 through at least 2006, Cephalon promoted Actiq "for non-cancer patients to use for such maladies as migraines, sickle-cell pain crises, injuries, and in anticipation of changing wound dressings or radiation therapy." Cephalon also promoted Actiq for use in patients for whom "it could have ***life-threatening*** results."

116. Cephalon paid $425 million to resolve the charges. It also entered into a Corporate Integrity Agreement with the Office of Inspector General of the Department of Health and Human Services, under which it agreed to notify doctors of the settlement terms and give doctors a means by which to report questionable conduct of Cephalon sales representatives. Cephalon was also required to disclose payments to doctors on its website, and to regularly certify that it has an effective compliance program.

117. The dangers of abuse of opioids cannot have been a surprise for Defendants. Setting aside the long-understood general concerns about the addictive nature of opioid drugs, physicians and researchers had identified abuse issues with Purdue's original and less powerful opioid drug, MS Contin, long before Purdue ever introduced the more potent OxyContin. In a 1990 medical journal article, the authors reported on a patient that described a "commonly used" approach to abuse Purdue's MS Contin product and noted that MS Contin had become "a highly desirable preparation for opioid abuse."[48]

118. In addition, a number of published clinical studies refuted Defendants' misstatements about the potential risks of addiction for opioid drugs, with some studies finding rates of prescription drug abuse in chronic pain patients as high as 45%. One study in 1995, the

[48] James C. Crews & Donald D. Denson, *Recovery of Morphine From a Controlled-Release Preparation: A Source of Opioid Abuse*, 66 CANCER 2642, 2642-43 (Dec. 15, 1990).

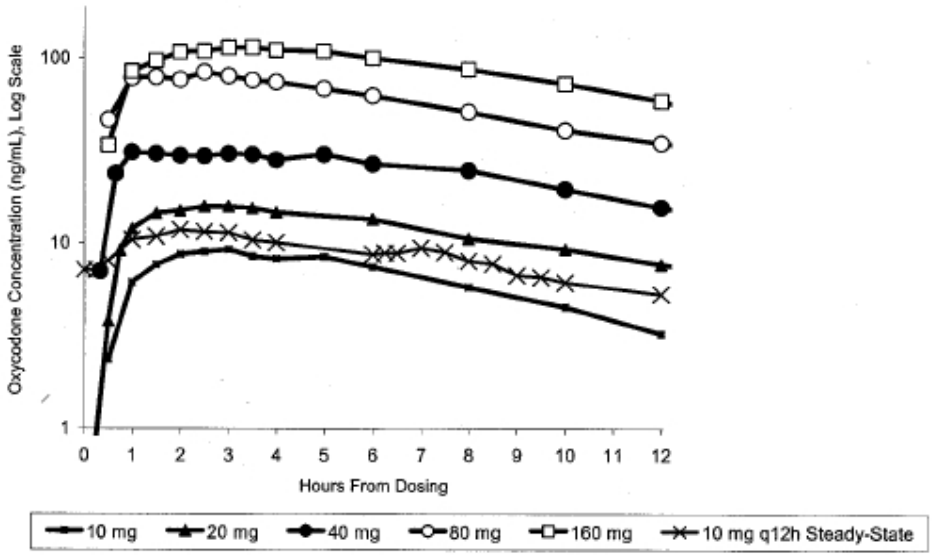
same year OxyContin was approved by the FDA, reported a 23% risk of abuse and dependence in chronic pain patients, while another study published in 1997 reported a 12% risk of abuse and dependence.[49]

119. Defendants misrepresented the addiction dangers of opioids. Cephalon's short-acting formulations include Actiq and Fentora which are immediately released to provide 4-6 hours of treatment to address "episodic" pain. But part of Cephalon's marketing campaign was to encourage the use of these short-acting opioids to be layered on top of a continuous course of long-acting opioid treatment. Both long-acting and short-acting kinds of opioids are highly addictive and, when layered on top of one another, pose even greater risks of addiction.

120. Defendants not only misrepresented the addictive nature of opioids, but also misrepresented their effectiveness. Purdue alleged that OxyContin, as an extended-release 12-hour pain medication, would have fewer "peaks and valleys" than immediate-release opioid drugs, thus having less of a euphoric effect on the patient and less potential for abuse than immediate-release opioid drugs. Once again, Purdue knew these claims were not true.

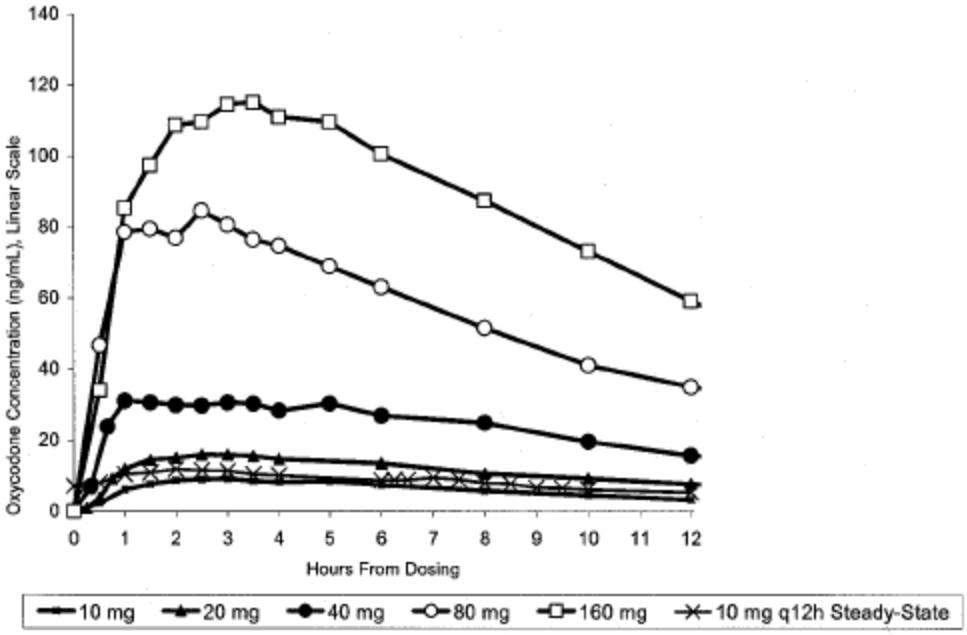
121. For example, Purdue used the following chart to show the level of OxyContin's active opioid ingredient, oxycodone, in a patient's blood over time.

[49] Van Zee, *supra* note 23 at 223 (collecting studies).



122. This chart appears to show a relatively consistent level of OxyContin in the blood over the claimed 12-hour dosage period of a single OxyContin pill. However, what Purdue did to make it appear relatively consistent and level, and what few patients would notice or understand, is that the vertical, y-axis, is on a logarithmic scale, not a linear scale like the x-axis. When the y-axis is converted to a linear scale like the x-axis as depicted below, the picture is quite different, showing a peak of concentration early in the 12-hour dosing period, followed by a significant tailing-off period. Such a tailing-off period would likely cause patients to seek another dose of OxyContin well before the end of the 12-hour period in an effort to seek a new "high," and is a seed for addiction and abuse of opioids.[50]

[50] Jim Edwards, *Who Signed Off on Purdue's Misleading OxyContin Chart? Judge May Want Answers*, CBS News, (Jan. 7, 2010), http://www.cbsnews.com/news/who-signed-off-on-purdues-misleading-oxycontin-chart-judge-may-want-answers/.



123. The FDA eventually required Purdue to refrain from making its claims about fewer "peaks and valleys" in marketing OxyContin.[51]

124. In 2013, Dr. David Egilman, a Brown University researcher and an expert on warning labels, accused Purdue of ignoring this data and its own research in pursuit of OxyContin profits. He attacked Purdue's 12-hour dosing claims as inaccurate, stating that the 12-hour dosing schedule puts patients on a "dangerous rollercoaster of withdrawal and relief." He continued and said "'the Q12 dosing schedule is an ***addiction producing machine***.'"[52]

125. Other untrue and deceptive marketing statements made by Purdue's sales forces included telling physicians that patients could stop using OxyContin abruptly without experiencing withdrawal symptoms, that patients would not develop tolerance to the drug, and that OxyContin, because it was an extended release opioid product, was less susceptible to abuse.

[51] Plea Agreement, Attachment F, *supra* note 47 ¶¶22-24.
[52] Harriet Ryan, Lisa Girion & Scott Glover, *'You Want a Description of Hell?' OxyContin's 12-Hour Problem*, L.A. TIMES (May 5, 2016), *available at* http://www.latimes.com/projects/oxycontin-part1/.

None of that was true.[53] The misrepresentation that patients would not develop tolerance was particularly egregious – in fact, Purdue eventually created higher dosage forms of OxyContin specifically for opioid-tolerant patients.[54]

126. As a result of these various forms of improper and deceptive marketing actions, Purdue and other Defendants found themselves in the crosshairs of various federal investigations. In May 2007, Purdue ended up settling federal allegations that it had introduced misbranded drugs in interstate commerce. The settlement included over $700 million in payments to the United States government, and guilty pleas by three of Purdue's former executive officers. In a company statement, Purdue acknowledged that "some employees made, or told other employees to make, certain statements about OxyContin to some healthcare professionals that were inconsistent with the FDA-approved prescribing information for OxyContin and the express warning it contained about risks associated with the medicine."[55] And in 2008 Cephalon paid $425 million for off-label marketing.

127. Despite these significant penalties and promises to cease their deceptive marketing of opioids, Defendants nonetheless continued to misrepresent and deceptively market its opioid products throughout the United States, including in the TJSA. In fact, Defendants spent millions to market their drugs as safe and effective for long-term use. Specifically, between 2000 and 2015, upon information and belief, Actavis spent up to $5 million quarterly; Cephalon's quarterly spending climbed steadily from under $1 million in 2000 to peak at more than $27 million in a single year (2007); and Endo's quarterly spending climbed from between

[53] *Id.*

[54] Anjelina Pokrovnichka, Medical Officer, U.S. Food & Drug Administration, *History of OxyContin: Labeling and Risk Management Program*, FDA 1, 7 (2008), https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndLifeSupportDrugsAdvisoryCommittee/UCM248776.pdf (last visited June 11, 2017).

[55] Shannon Henson, *Purdue, Employees To Pay $700M In OxyContin Case*, Law360 (May 10, 2007), http://docplayer.net/193993-U-s-food-and-drug-administration.html.

$2 and $4 million per quarter to a high of over $10 million per quarter in 2007 ($38 million total for the year) following the roll-out of Opana ER. This flood of funds was used to promote, through various avenues, the alleged safety of opioids in treating chronic pain.

128. For example, until October 1, 2015, Purdue operated a pain management advocacy website, www.inthefaceofpain.com. For much of the time the website was available, the site did not include any prominent branding that indicated it was sponsored by Purdue other than a small copyright notice at the bottom of the website. The site hosted a number of written and video testimonials from physicians advocating for the use of opioid products for chronic pain treatment. From March 2014 to March 2015, the website – which was available across the United States, including in the TJSA – received more than 250,000 page views.

129. Unbeknownst to the visitors of the site, Purdue had made payments totaling approximately $230,000 to 11 of the advocates featured on the website for meetings, speaker fees, and travel costs between 2008 and 2013. One of those featured advocates was none other than the aforementioned Dr. Portenoy. Purdue failed to disclose these financial connections on an otherwise unbranded website, thus causing patients to be misled by the potential biases of the advocates and their statements supporting the use of opioids for treatment of various forms of chronic pain.[56]

130. Purdue also failed to place any warnings of opioid abuse on the www.inthefaceofpain.com website. The site linked to a document that briefly mentioned opioid abuse, but the website itself failed to mention the dangers of abuse.[57] This too was unfair and deceptive marketing given that Purdue has known about the dangers of opioid abuse for many

[56] Att'y Gen. of the State of N.Y.,¶¶18-19, *In the Matter of Purdue Pharma L.P.*, Assurance No. 15-151 (Aug. 19, 2015).
[57] *Id.*

years, as evidenced by the black box warning Purdue was required to place on the OxyContin product packaging.

131. Defendants have also spent significant amounts of money advertising in medical journals to spread their misrepresentations of opioid use for chronic pain. For example, Purdue launched a 2012 advertising campaign in medical journals presenting "pain vignettes." These "vignettes" were case studies of hypothetical patients with chronic pain conditions, such as a "writer with osteoarthritis of the hands," that implicitly stated OxyContin would be a proper treatment for arthritis pain and would allow the writer to continue working effectively. These misleading advertisements either understated or failed to acknowledge the limited use of opioids for treatment of these types of pain, and the risks of abuse and addiction presented by opioid drugs.[58]

132. In December 2011, Cephalon widely disseminated a journal supplement titled "Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)" to Anesthesiology News, Clinical Oncology News, and Pain Medicine News – three publications that are sent to thousands of anesthesiologists and other medical professionals. Despite the FDA's 2007 warning that Fentora should not be used to treat any type of short-term pain, the Special Report openly promotes Fentora for "multiple causes of pain" – and not just cancer pain.

133. Similarly in 2011, Purdue published an educational pamphlet entitled *Providing Relief, Preventing Abuse*, targeted at prescribing physicians and law enforcement. In the pamphlet, Purdue improperly downplayed the risks of addiction and highlighted signs of opioid abuse that were more common with heroin, such as skin popping and track marks, but provided

[58] *See Ohio v. Purdue Pharma, L.P.*, No. CV 17 CI 000261, Compl. ¶ 38 (Ohio Ct. C. P. May 31, 2017) (hereinafter "Ohio Complaint").

little guidance on the more common signs of prescription opioid abuse, such as seeking early refills or patients pressuring their physician for increased dosage amounts. *Providing Relief, Preventing Abuse* was available nationally and was intended to reach TJSA prescribing physicians.

134. *Providing Relief, Preventing Abuse* also misrepresented and disguised opioid addiction by supporting the idea that drug-seeking behavior could be a sign of "pseudoaddiction" instead of actual addiction. The pamphlet noted that pseudoaddiction had been discussed in medical literature to describe "[drug-seeking behaviors] in patients who have pain that has not been effectively treated," thus implying that seeking more opioids may actually be a medically driven condition when in fact it is not. Notably, Purdue did not disclose that there was no scientific evidence to justify the concept of pseudoaddiction or that the term had been coined by a Purdue executive.

135. Purdue's use of the concept of pseudoaddiction in the 2011 pamphlet was not new. In a 2007 publication that it sponsored with Cephalon – a book titled *Responsible Opioid Prescribing–A Physician's Guide*, written by Dr. Scott M. Fishman – the concept of pseudoaddiction was highlighted as a condition for physicians to watch out for as a reason to prescribe ***more***, ***not fewer***, opioid drugs. The book noted that signs of pseudoaddiction include obtaining opioids from more than one physician, hoarding opioids, demanding behavior, and taking opioid drugs for an extended period. The book also included a table with certain behaviors identified as "Behaviors LESS indicative of addiction" that included hoarding medications, taking someone else's pain medication, aggressively complaining to a doctor for more drugs, and using more opioids than recommended. Again, no disclosure was made to justify or support the concept of pseudoaddiction or to rationalize why hoarding medications,

using other people's pain medications, or using more opioids than recommended should be less indicative instead of more indicative of addiction.[59]

136. The 2012 edition of *Responsible Opioid Prescribing* is still available for sale online and reiterates the teaching that pseudoaddiction is real. The book was sponsored by Cephalon and Purdue and distributed by Endo and Purdue: Upon information and belief, Purdue spent over $100,000 to support distribution of the book. Cephalon spent $150,000 to purchase copies of the book in bulk and distributed it through its pain sales force to 10,000 prescribers and 5,000 pharmacists. Endo spent $246,620 to buy copies of *Responsible Opioid Prescribing* (2007), which was then distributed by Endo's sales force.

137. Actavis tried the same strategy. In 2005, the company commissioned a consultant's report on the barriers to entering the prescription-opioid market. That report concluded that Actavis would have to contend with "concerns regarding the safety and tolerability" of opioids, as well as the fact that "physicians have been trained to evaluate the supporting data before changing their respective practice behavior." The report recommended that Actavis therefore implement a "[p]ublication strategy based on placing in the literature key data that influence members of the target audience," with an "emphasis . . . on ensuring that the message is believable and relevant to the needs of the target audience." Specifically, this would entail relying on "published references" and "developing and placing publications that demonstrate [the] efficacy [of opioids] and [their] safety/positive side effect[s]." Whether scientists actually agreed with those publications would be irrelevant: As the report put it, "greater support" for opioids' use would come from "either actual or ***perceived*** 'scientific

[59] Scott M. Fishman, Responsible Opioid Prescribing –A Physician's Guide 62-63 (2007).

exchange.'" (emphasis added). Articles matching the report's description later appeared in the *Journal of Pain Medicine* and the *Journal of the American Geriatrics Society*.

138. Endo published misleading material, too. In 2007, it commissioned a supplement in the *Journal of Family Practice* titled "Pain Management Dilemmas in Primary Care: Use of Opioids." That supplement minimized the risks of opioid addiction and misleadingly touted screening tools, dosage limits, and toxicology testing as a "maximally structured approach" that could keep addiction-prone patients away from prescription opioids. Endo published another pamphlet titled "Living with Someone with Chronic Pain." That pamphlet misleadingly suggested that addiction was not a significant concern for chronic pain patients, since "[m]ost health care providers who treat people with pain agree that most people do not develop an addiction problem." Endo distributed thousands of copies of both publications nationwide, including in the TSJA.

139. Not content to spread misinformation about opioids alone, Defendants promoted the opioid drug market generally, primarily through the creation and support of industry groups that were nominally presented to the public as independent entities but in reality were heavily funded by the pharmaceutical companies. All told, opioid manufacturers, including Defendants, paid nearly $9 million between 2012 and 2017 to advocacy groups and professional societies operating in the area of opioids policy. Payments from Purdue account for roughly half of that funding.[60]

140. One of the most prominent of these industry groups was the American Pain Foundation ("APF"). Overall, the APF reportedly received more than $10 million in funding

[60] *Fueling an Epidemic, Report Two: Exposing the Financial Ties Between Opioid Manufacturers and Third-Party Advocacy Groups*, U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Member's Office at 1.

from opioid drug manufacturers between 2007 and 2012, when the organization was finally shut down. Of that amount, Purdue contributed approximately $1.7 million.[61] APF's total budget for 2010 was roughly $3.5 million with projected receipts of approximately $2.9 million from drug companies. By 2011, APF was wholly dependent on incoming grants from defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit.

141. While presenting itself to the public as an independent patient advocacy organization, the APF was in fact advocating for opioid manufacturers.

142. For example, in 2001, APF published a guide titled *Treatment Options: A Guide for People Living with Pain*. The guide, produced with grants from Cephalon and Purdue, misrepresented the risks and benefits associated with chronic opioid therapy. The guide is still available online and was intended to reach Oklahoma and TJSA prescribers and pharmacists.

143. *Treatment Options* deceptively asserts that the long-term use of opioids to treat chronic pain could help patients function in their daily lives by stating that, when "used properly," opioids "give [pain patients] a quality of life [they] deserve." *Treatment Options* makes this assertion despite a complete lack of data to support that statement. Indeed, available data demonstrates the contrary – patients taking prescription opioids on a long-term basis to treat chronic pain are *less* likely to participate in normal, everyday activities.

144. *Treatment Options* also asserts that "[r]estricting access to the most effective medications for treating pain is not the solution to drug abuse" and states that addiction can be curbed by entering into an "agreement" with one's physician. *Treatment Options* nowhere discloses that such "agreements" or other screening tools have never been shown to curb addiction or make it easier to identify and manage.

[61] *See* Ohio Complaint ¶67.

145. Endo relied on the APF, as well. In exchange for massive financial support, Endo provided substantial assistance to, and exercised editorial control over, the deceptive and misleading messages that APF made through its National Initiative on Pain Control ("NIPC"). That included developing, specifying, and reviewing content, as well as distributing materials that promoted opioid use for chronic pain. Its direct role in the NIPC allowed Endo to track the distribution of NIPC materials, which let the company continuously assess the scope and reach of its marketing efforts.

146. The APF also provided "patient representatives" for *Partners Against Pain*, a Purdue-branded website used to promote OxyContin and other opioid drugs. In 2011, Purdue hired an APF consultant to help with the launch of the website and orchestrate a media campaign. Far from being independent, the APF consultant was required to discuss and rehearse the delivery of Purdue's campaign messages. Additionally, all decisions regarding the content on the *Partners Against Pain* website were within the sole discretion of Purdue.

147. The APF, thanks to its financial support from Defendants, was willing to make public statements to support Defendants' deceptive marketing messages about opioids. The APF testified on Purdue's behalf at a July 2007 Senate Judiciary Committee hearing – in the shadow of Purdue's May 2007 settlement with the government over misstatements about OxyContin – that OxyContin was "rarely" addictive and was less addictive than other opioids. In addition, the APF testified that addiction was a "rare problem" for patients who used opioids for chronic pain, and that there was "no causal effect . . . between the marketing of OxyContin and the abuse and diversion of the drug." No scientific support for those statements was provided.

148. In 2011, thanks again primarily to Defendants' financial support, the APF published and distributed *A Policymaker's Guide to Understanding Pain & Its Management*.

This guide, still available online today, incorrectly states that scientific studies support using opioids for the treatment of chronic pain in order to improve patients' ability to function.

149. It also contains misrepresentations such as: "Less than 1 percent of children treated with opioids become addicted." Similarly, the guide states: "Multiple clinical studies have shown that long-lasting opioids, in particular, are effective in improving: [d]aily function, [p]sychological health, [o]verall health-related quality of life for people with chronic pain." However, the study cited in support of this statement specifically noted that there were no studies demonstrating the long-term safety of opioids, and that "[f]or functional outcomes, the other [studied] analgesics were significantly more effective than were opioids." Lastly, the guide misrepresents the risks of addiction, claiming that pain had been generally "undertreated" due to "misconceptions about opioid addiction."

150. Through two other industry groups formed to shill for the opioid manufacturers, Defendants supported the publication of guidelines that recommended the use of opioids to treat chronic pain. Those industry groups – the American Pain Society ("APS") and the American Academy of Pain Medicine ("AAPM") – received roughly $2.9 million from opioid companies, including Purdue and Endo, in 2010 and 2011.

151. The guidelines published jointly in 2009 by APS and AAPM (the "2009 Guidelines"), were drafted by 21 panel members, 14 of whom received support from opioid manufacturers, including Purdue, Cephalon, Actavis, and Endo. One of the panel members was the ubiquitous Dr. Portenoy. Another panel member, Joel Saper, ultimately resigned from the panel over his concerns about Defendants' influence over the creation of the guidelines.

152. The 2009 Guidelines were widely disseminated as a form of third-party validation to convince physicians to prescribe opioid drugs for all forms of chronic pain. While

acknowledging that there was limited evidence, the 2009 Guidelines promote opioids as "safe and effective" for chronic pain treatment and indicated that the risk of addiction was manageable for all classes of patients regardless of past drug abuse history. The 2009 Guidelines also suggest, shockingly, that "opioids have no maximum or ceiling dose." Defendants relied heavily on this message when courting prescribers. For years, sales representatives from Endo, Actavis, and Purdue discussed the Guidelines with physicians during sales visits.

153. The damage caused by the 2009 Guidelines was extensive. In addition to influencing countless treating physicians, the 2009 Guidelines' unsupported claims regarding the safe use of opioids to treat chronic pain have been cited over 1,600 times in academic literature, and were reprinted in the February 2009 Journal of Pain. The 2009 Guidelines continue to be available online, including in the TJSA.

154. AAPM also maintains a "Corporate Relations Council" which it describes as offering "many opportunities to interact with over 2,000 dedicated pain physicians." Participation in the Council costs $25,000 per year, and entitles members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations. Defendants Endo, Purdue, Cephalon, and Actavis were members of the council and presented deceptive programs to doctors who attended this annual event.

155. Defendants also presented deceptive continuing medical education programs – professional educational programs provided to doctors. Physicians are required to attend a certain number of Continuing Medical Education ("CME") programs each year to maintain their license. Doctors rely on CMEs not only to satisfy their license requirements but to stay up to date with new developments in medicine. Defendants, through their sponsorship of various

CMEs, used these programs to promote chronic opioid therapy and inflate the benefits of opioid use while omitting the adverse effects of using opioids to treat chronic pain.

156. The American Medical Association ("AMA") has recognized that support from drug companies with a financial stake in the content being promoted in CMEs "creates conditions in which external interests could influence the availability and/or content" of the programs and urges that "[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the educational subject matter."

157. Nonetheless, Defendants knowingly sponsored and exercised control over a number of CMEs.

158. For example, Cephalon sponsored a CME titled *Optimizing Opioid Treatment for Breakthrough Pain*, which was available online beginning September 28, 2007 and was intended to reach Oklahoma prescribers. The CME misleadingly taught that Cephalon's Actiq and Fentora improved patients' quality of life and allowed for more activities when taken in conjunction with long-acting opioids. It also misleadingly minimized the risks associated with increased opioid doses by explaining that NSAIDs were less effective than opioids for the treatment of breakthrough pain because of their dose limitations, without disclosing the heightened risk of adverse events on high-dose opioids. This CME remains available online today and was intended to reach Oklahoma prescribers.

159. Cephalon similarly used an educational grant to sponsor the CME *Breakthrough Pain: Improving Recognition and Management*, which was offered online beginning March 31, 2008 and was intended to reach Oklahoma prescribers. The allegedly educational document deceptively omitted Actiq's and Fentora's tolerance limitations, cited examples of patients who experienced pain from accidents, not from cancer, and, like Cephalon's *Optimizing Opioid*

Treatment CME, taught that Actiq and Fentora were the only products on the market that would take effect before the breakthrough pain episode subsided. This CME was available online and was intended to reach Oklahoma prescribers.

160. The NIPC also distributed a series of CMEs, focusing on "key topic[s] surrounding the use of opioid therapy." The CMEs – specifically, those titled "Persistent Pain in the Older Patient" and "Persistent Pain in the Older Adult" – misrepresented the prevalence of addiction and erroneously stated that opioids have "possibly less potential for abuse" in elderly patients than in younger patients. Those CMEs also misleadingly stated that opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." Endo sponsored all of those CMEs, each of which was seen by an estimated 60,000 physicians.

IV. Defendants' Failure to Prevent Opioid Diversion

161. In parallel with the popularization of opioid drugs through, among other things, Defendants' relentless marketing campaign, the federal government recognized there was a need to tightly regulate opioids to ensure these powerful drugs were only distributed to patients with a legitimate medical need. The Controlled Substances Act, 21 U.S.C. §§ 801 *et seq.*, ("CSA"), was originally enacted in 1970 to ensure that dangerous and addictive drugs, including prescription opioids, would be carefully monitored and regulated on the market.

162. The CSA creates a legal framework for the manufacturing and distribution of controlled substances. Congress passed the CSA partly out of a concern about the widespread diversion of controlled substances out of legitimate channels and into the illegal market. *See* H.R. Rep. No. 91-1444, (1970), reprinted in U.S.C.C.A.N. 4566, 4572.

163. Prescription opioids with a high potential for addiction, or for which abuse may lead to severe psychological or physical dependence, are categorized under Schedule II of the CSA and the corresponding regulations. *See* 21 C.F.R. § 1308.12. Drugs listed on Schedule II

include non-synthetic derivatives of the opium poppy (such as codeine and morphine, which are also called "opiates"), partially synthetic derivatives (such as hydrocodone and oxycodone), and fully synthetic derivatives (such as fentanyl and methadone).

164. To prevent unauthorized users from obtaining opioids, the CSA creates a distribution monitoring system for controlled substances. At the heart of this system are registration and tracking requirements imposed upon any person or entity authorized to handle controlled substances.

165. The supply chain for prescription opioids, regulated under the CSA, begins with the manufacture and packaging of the pills. The manufacturers, such as Defendants, then transfer the pills to distribution companies, which then supply opioids to hospitals, pharmacies, doctors, and other healthcare providers, which in turn dispense the drugs to patients. Manufacturers like Defendants are thus regulated both as manufacturers under the CSA when they produce and package opioid drugs *and* as distributors when they ship the pills to the next party in the supply chain.

166. Each participant in the supply chain shares the responsibility for controlling the availability of prescription opioids and has a duty to evaluate the party to whom it is providing opioids. Opioid "diversion" occurs whenever the drugs are transferred from a legitimate channel of distribution or use to an illegitimate channel of distribution or use. Diversion can occur at any point in the opioid supply chain, including at the point of original shipment by a manufacturer such as Purdue. When a manufacturer ships the opioids, it assumes those duties imposed on distributors since the manufacturer, at that point in the supply chain, is itself distributing the drugs.

167. For example, at the level of manufacturing and distribution, diversion occurs whenever manufacturers allow opioids to be lost or stolen in transit, or by filling suspicious orders of opioids from wholesale distributors or pharmacies. Suspicious orders include orders of an unusually large size, orders that are disproportionately large in comparison to the population of a region served by the wholesale distributors or pharmacies, orders that deviate from a normal pattern, and/or orders of unusual frequency.

168. Defendants, as manufacturers and distributors under the CSA, have a number of duties that they must fulfill under the CSA to prevent diversion, of which the most important are ensuring the physical security of opioid drugs and maintaining robust records of every shipment of opioids it produces.

169. All opioid distributors – including Defendants, which are not only manufacturers, but are also regulated as distributors under the CSA whenever they ship the opioids they have produced – are required to maintain effective controls against opioid diversion. They are also required to create and use a system to identify and report downstream suspicious orders of controlled substances to law enforcement. Suspicious orders include orders of unusual size, orders deviating substantially from the normal pattern, and orders of unusual frequency. To comply with these requirements, manufacturers and distributors must know their customers, report suspicious orders, conduct due diligence, and terminate orders if there are indications of diversion.

170. The DEA's Automation of Reports and Consolidation Orders System ("ARCOS") is an automated drug reporting system which monitors the flow of Schedule II controlled substances from their point of manufacture through commercial distribution channels to the point of sale. ARCOS accumulates data on manufacturers and distributors' controlled substances

acquisition/distribution transactions, which are then summarized into reports used by the DEA to identify any diversion of controlled substances into illicit channels of distribution. Each person or entity that is registered to distribute ARCOS-reportable controlled substances, which includes Defendants, must report its distribution and acquisition transactions to the DEA.

171. Acquisition and distribution transaction reports must provide data on each acquisition to inventory (identifying whether it is, *e.g.*, by purchase or transfer, return from a customer, or supply by the federal government) and each reduction from inventory (identifying whether it is, *e.g.*, by sale or transfer, theft, destruction or seizure by government agencies) for each ARCOS-reportable controlled substance. *See* 21 U.S.C. § 827(d)(l); 21 C.F.R. §§ 1304.33(d), (e). Inventory that has been lost or stolen must also be reported separately to the DEA within one business day of discovery of such loss or theft.

172. In addition to filing acquisition/distribution transaction reports, each registrant is required to maintain on a current basis a complete and accurate record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of. *See* 21 U.S.C. § 827(a)(3); 21 C.F.R. §§ 1304.21(a), 1304.22(b). It is unlawful for any person to negligently fail to abide by the recordkeeping and reporting requirements.

173. In order to maintain registration, manufacturers and distributors must also maintain effective controls against diversion of controlled substances. When determining if a manufacturer and/or distributor has provided effective controls, the DEA Administrator refers to the security requirements set forth in §§ 1301.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion. *See* 21 C.F.R. § 1301.71.

174. To combat the problem of opioid diversion, the DEA has provided guidance to manufacturers and distributors on the requirements of suspicious order reporting in numerous venues, publications, documents, and final agency actions.

175. Since 2007, the DEA has hosted at least five conferences to provide registrants with updated information about diversion trends and regulatory changes that affect the drug supply chain, the distributor initiative, and suspicious order reporting. All of the major manufacturers and distributors, including Defendants, attended at least one of these conferences. The conferences allowed the registrants to ask questions and raise concerns. Registrants could also request clarification on DEA policies, procedures, and interpretations of the CSA and implementing regulations.

176. Accordingly, the CSA acts as a system of checks and balances from the manufacturing level through delivery of the pharmaceutical drug to the ultimate patient or customer. Every person or entity who manufactures, distributes, or dispenses opioids must obtain a "registration" with the DEA. Registrants at every level of the supply chain must fulfill their obligations under the CSA, otherwise controlled substances move from the licit to the illicit marketplace, and there is great potential for harm to the general public.

177. However, over time and despite the regulated controlled substances supply chain under the CSA, opioid diversion now occurs in the United States at an alarming rate, including throughout the TJSA. In recent years, the number of people who take prescription opioids for non-medical purposes is greater than the number of people who use cocaine, heroin, hallucinogens, and inhalants combined.

178. In fact, in addition to the CSA and its associated regulations intended to control the flow of opioids, the DEA formed a specific division to address diversion issues – the

Diversion Control Division – with a stated mission "to prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs."[62]

179. The issue of diversion is directly linked to, and is a result of, Defendants' marketing barrage. In a 2006 policy statement issued by the DEA and the Diversion Control Division, the linkage between increased marketing and the diversion of opioid drugs was explicitly acknowledged: "The large amount of [the drug] available in the marketplace may have increased opportunities for abuse and diversion. Both DEA and [the manufacturer of the drug] have stated that an increase in a drug's availability in the marketplace may be a factor that attracts interest by those who abuse and divert drugs."[63]

180. Given their trusted role in the controlled substance supply chain, manufacturers such as Defendants are acutely aware of the opioid diversion issue, particularly given the granular data they possess about the ultimate distribution of their drugs, which includes both the data required to be submitted to ARCOS and their own internal data analysis systems.

181. An investigative journalism report in the *L.A. Times* published in July 2016 illustrates both the type of information Defendants obtained about opioid diversion, as well as the blind eye they turned to diversion.

182. In the summer of 2008, a single doctor at a California clinic began prescribing OxyContin.

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[62] U.S. Dep't of Justice, *Drug Enforcement Administration Diversion Control Division*, https://www.deadiversion.usdoj.gov/Inside.html, (Mar. 4, 2018).

[63] Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 5,2716; 5,2722 (Sept. 6, 2006) (quoting U.S. Gen. Acct. Office, GAO-04-110 *Prescription Drugs OxyContin Abuse and Diversion and Efforts to Address the Problem* (Dec. 2003), http://www.gao.gov/new.items/d04110.pdf.).

> In a single week in September, [the doctor] issued orders for 1,500 pills, more than entire pharmacies sold in a month. In October, it was 11,000 pills. By December, she had prescribed more than 73,000, with a street value of nearly $6 million. At its headquarters in Stamford, Conn., Purdue Pharma, the maker of OxyContin, tracked the surge in prescriptions. A sales manager went to check out the clinic and the company launched an investigation, concluding that [the clinic] was working with a corrupt pharmacy in Huntington Park to obtain large quantities of OxyContin.[64]

183. Yet despite this direct knowledge of ongoing diversion, "Purdue did not shut off the supply of highly addictive OxyContin and did not tell authorities what it knew about [the clinic] until several years later when the clinic was out of business and its leaders indicted."[65]

184. This was not an isolated incident. Defendants have collected and tracked the distribution of its opioid drugs all the way down from their initial distribution to specific prescribing records of individual doctors. The *L.A. Times*, through its investigation, found that:

> [F]or more than a decade, Purdue collected extensive evidence suggesting illegal trafficking of OxyContin and, in many cases, did not share it with law enforcement or cut off the flow of pills. A former Purdue executive, who monitored pharmacies for criminal activity, acknowledged that even when the company had evidence pharmacies were colluding with drug dealers, it did not stop supplying distributors selling to those stores. Purdue knew about many suspicious doctors and pharmacies from prescribing records, pharmacy orders, field reports from sales representatives and, in some cases, its own surveillance operations, according to court and law enforcement records, which include internal Purdue documents, and interviews with current and former employees.[66]

185. Moreover, far from just tracking the distribution of its opioid drugs to wholesale distributors and pharmacies, Defendants, upon information and belief, actively kept track of specific doctors that were the most prolific in prescribing its opioid drugs. Purdue, for example, maintains "a confidential roster of physicians suspected of recklessly prescribing to addicts or

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[64] Harriet Ryan, Scott Glover & Lisa Girion, *More than 1 Million OxyContin Pills Ended up in the Hands of Criminals and Addicts. What the Drugmaker Knew*, L.A. TIMES (July 10, 2016), *available at* http://www.latimes.com/local/la-me-oxycontin-drug-ring-part-2-20160710-story.html.
[65] *Id.*
[66] *Id.*

dealers. Purdue calls that list Region Zero and has been adding names to it since 2002. A [*L.A.*] *Times* investigation in 2013 revealed the existence of the list. At that time, the company acknowledged that there were more than 1,800 doctors in Region Zero."[67]

186. This ability to specifically identify and track opioid diversion activities by doctors and pharmacies is a known technical capability within Purdue. In fact, a former Purdue executive described this capability as a "gold mine." "With a few keystrokes on his computer at Purdue, Jack Crowley [a former DEA employee and subsequently an executive (now retired) at Purdue responsible for compliance with the federal controlled substances law] could identify pharmacies around the country that were moving a staggering volume of [OxyContin 80-mg pills] and almost nothing else. 'I could punch it in at any time . . . Bang,' Crowley told the Times. 'I was sitting on a gold mine.'"[68]

187. Yet despite this ability to specifically identify sources of opioid diversion, Jack Crowley told the L.A. Times that "in the five years he spent investigating suspicious pharmacies, Purdue never shut off the flow of pills to any store."[69]

188. Given Defendants' legal requirements under the CSA, including their reporting obligations, and their vast data collection and analysis capabilities enabling them to identify opioid diversion, Defendants should have identified opioid diversion activities in the TJSA and taken actions to limit the flow of opioids into the TJSA to prevent diversion.

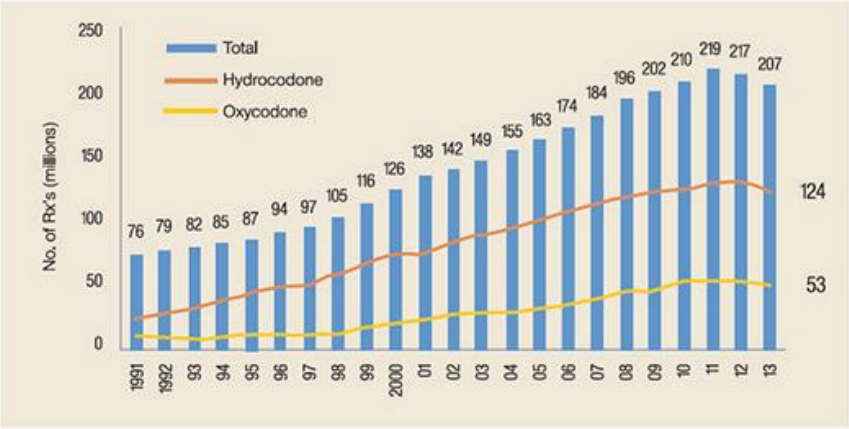
V. The Devastating Impact of Defendants' Deceptive Marketing and Failure to Prevent Diversion

189. Not surprisingly, the increased marketing of opioids for many forms of chronic pain relief, supported by Defendants' numerous direct and indirect misleading and deceptive

[67] *Id.*
[68] *Id.*
[69] *Id.*

claims, led to rampant growth of opioid prescriptions for pain relief. And from the rampant growth of prescriptions came widespread opioid diversion, which, despite having the data to detect and prevent, Defendants have continued to enable by supplying opioids with reckless abandon. Reflecting Dr. Warren Cole's fear from 60 years ago, the greatly expanded use of opioids for chronic pain has indeed led to what he termed a "hideous spectacle," in which patients that begin taking opioids for various forms of chronic pain eventually progress to abuse and addiction, relying on ever-increasing dosages of opioids for non-medical purposes and turning to illegal sources to obtain their opioid fix through diversion.

190. The number of people who now take prescription opioids for non-medical purposes is greater than the number of people who use cocaine, heroin, hallucinogens, and inhalants combined.[70] Indeed, by 2004, OxyContin had already become the most commonly abused prescription opioid drug in the United States.[71]

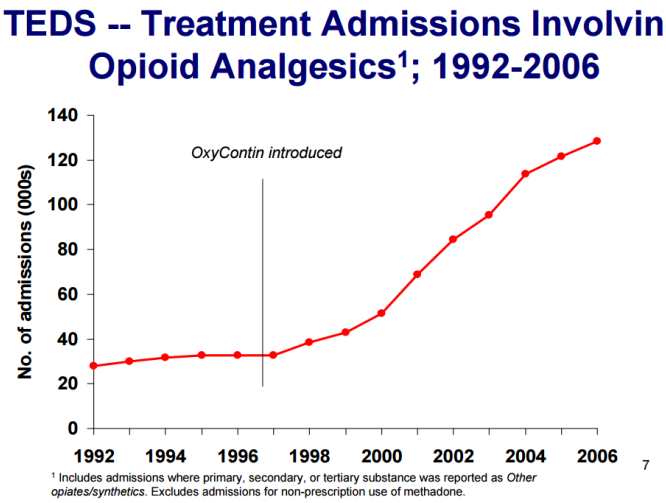


Opioid Prescriptions Dispensed by US Retail Pharmacies IMS Health, Vector One: National, years 1991-1996, Data Extracted 2011. IMS Health, National Prescription Audit, years 1997-2013, Data Extracted 2014.

[70] Beth Han, et al., *Nonmedical Prescription Opioid Use and Use Disorders Among Adults Aged 18 Through 64 Years in the United States, 2003-2013*, 314 AM. J. MED. ASS'N 1468-72 (2015) ("In 2013, prescription opioids were involved in more deaths (>16 200) than all illicit drugs combined.").

[71] Theodore J. Cicero, James A. Inciardi & Alvaro Munoz, *Trends in Abuse of OxyContin and Other Opioid Analgesics in the United States: 2002-2004*, 6 J. PAIN 662 (2005).

191. A study published by the FDA illustrates the effects of Defendants' marketing of opioids and the subsequent diversion of opioids for non-medical purposes. The following chart shows the dramatic increase in the number of patient admissions for treatment of opioid addiction and abuse.[72]



192. The explosion in opioid abuse is linked to Defendants' expansive and deceptive marketing of opioid prescriptions. According to the 2009 National Survey on Drug Use and Health, "over 70 percent of people who abused prescription pain relievers got them from friends or relatives, while approximately 5 percent got them from a drug dealer or from the Internet."[73]

193. Every year, millions of people in the United States now misuse and abuse opioid pain relievers that can lead to addiction, overdose, and death. The overdose rate among American Indians, including Cherokee Nation citizens, is significantly higher than the rest of the population.[74]

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[72] Catherine Dormitzer, *Epidemiological Findings of Drug Misuse/Abuse in the United States: Oxycontin*, 7 U.S. Food & Drug Admin. (Sept. 24, 2009), https://tinyurl.com/ycusa2fm.

[73] Exec. Office of the President of the U.S., *Epidemic: Responding to America's Prescription Drug Abuse Crisis* 1, 1 (2011), https://www.ncjrs.gov/pdffiles1/ondcp/rx_abuse_plan.pdf (last visited June 9, 2017).

[74] Centers for Disease Control and Prevention, *Prescription Opioid Overdose Data*, (2017), https://www.cdc.gov/drugoverdose/data/overdose.html (stating overdose rates were higher among American Indians).

194. Within the last 20 years, the abuse of prescription narcotic pain relievers has emerged as a public health crisis in the United States. Overdose deaths involving prescription opioids have quadrupled since 1999.

195. In 2011, the Centers for Disease Control ("CDC") reported that overdose deaths from prescription opioids had reached epidemic levels. That year, 16,917 people died from prescription opioid related overdoses, according to the CDC and the National Center for Health Statistics National Vital Statistics. Since then, the death toll has continued to rise. In 2014, 18,893 people died from prescription opioid related overdoses. In 2015, that number increased again to 22,598.

196. Deaths from synthetic opioids have continued to rise with "more than an exponential increase" in recent years. The CDC has reported that the number of prescription-opioid-related deaths increased by 10.6% in 2016, and estimates that 2017 "will be at least as steep as 2016, if not steeper."[75]

197. In general, American Indians are more likely than other racial/ethnic groups in the United States to die from drug-induced deaths. Among American Indian tribes, the Cherokee Nation has been hit particularly hard by the effects of Defendants' marketing efforts and the diversion of Defendants' opioid drugs. Oklahoma, where the vast majority of Cherokee Nation citizens reside, leads the country in opioid abuse. In recent years, it has ranked number one nationally for the non-medical use of prescription opioids for adults, and it currently ranks as the state with the fifth highest number of drug overdose deaths in the United States. From 2007 to 2012, hydrocodone or oxycodone caused more overdose deaths in Oklahoma than alcohol,

[75] Christopher Ingraham, *CDC releases grim new opioid overdose figures: 'We're talking about more than an exponential increase,'* Wash. Post (Dec. 21, 2017), https://www.washingtonpost.com/news/wonk/wp/2017/12/21/cdc-releases-grim-new-opioid-overdose-figures-were-talking-about-more-than-an-exponential-increase/?utm_term=.81132b36ed6e.

methamphetamine, cocaine, heroin, and all other illegal drugs combined. Deaths of Cherokee Nation citizens significantly contribute to these statewide statistics.

198. The Cherokee Nation has taken proactive measures in its own health care system to fight against prescription opioid abuse. The Cherokee Nation was an early adopter of information technologies to combat opioid abuse. Cherokee Nation health care providers implemented and relied on a prescription monitoring program ("PMP") before use of PMP was required elsewhere. Cherokee Nation doctors access and review their patients' prescription histories directly at the point of care. The Cherokee Nation also cracked down on opioid distributors pushing Cherokee Nation doctors to prescribe opioids, and modified its prescription drug "formulary" to eliminate certain prescription opioids such as hydrocodone that are most widely abused. Additionally, health care providers at Cherokee Nation facilities stopped using hardcopy prescription forms, and transitioned to using electronic prescriptions, thus minimizing the risk of forgery or alteration.

199. However, in the face of Defendants' pervasive marketing of opioid drugs since the introduction of Purdue's OxyContin in 1996 and Defendants' failure to prevent diversion of opioid drugs, the Cherokee Nation's efforts have not been enough to stem the opioid abuse epidemic. Between 2003 and 2014 there were over 350 opioid-related deaths within the Cherokee Nation. Annual deaths from opioid-related overdoses more than doubled within the Cherokee Nation between 2003 and 2014. For adults within the Cherokee Nation, overdose deaths now outnumber deaths due to car accidents.

200. Deaths are just one facet of the opioid abuse epidemic. The CDC reports that for every opioid-related death in 2016, there was an average of 10 admissions into treatment, 26

emergency department visits for misuse, 115 people who used or are dependent on opioids, and 733 non-medical users.

201. According to public data from the DEA, over 2.75 billion milligrams of opioids were distributed in Oklahoma in 2015. That consisted of 97,068,585 and 87,234,447 total prescription dosage units of opioids filled in the TJSA in 2015 and 2016, respectively. Thus, over the two year period of 2015 to 2016, there were more than 184 million opioid dosage units filled in the TJSA. Based on the U.S. census population figures for the TJSA in 2015 and 2016, this amounts to 80.9 and 72.4 opioid dosage units for every single person in the TJSA (including children), or 107.5 and 96.2 opioid dosage units for every single adult in the TJSA, in each respective year.

202. Purdue alone was responsible for shipping over 12.4 million milligrams of four types of opioids – hydrocodone, oxycodone, hydromorphine, and fentanyl – into Oklahoma between 2006 and 2014. Between 2006 and 2014 Allergan accounted for roughly 53% of high-abuse[76] opioids shipped into the 14 counties comprising the TJSA.

203. Those numbers need to be put in context. Purdue produces OxyContin, which contains the opioid oxycodone as the active ingredient, in a range of extended-release tablet sizes containing 10-milligrams, 15-milligrams, 20-milligrams, 30-milligrams, 40-milligrams, 60-milligrams, and 80-milligrams of oxycodone.[77] Clinical guidelines for the safe prescription of opioids published by the CDC are based upon a measurement unit called "morphine milligram equivalents" ("MME") that compares a given opioid drug's efficacy with the efficacy of generic

[76] High-abuse opioids include oxycodone, hydrocodone, and oxymorphone in a range of tablet sizes of varying milligrams, including both immediate and extended release.
[77] *See* Purdue Pharma LP, *Full Prescribing Information* (Dec. 2016) http://app.purduepharma.com/xmlpublishing/pi.aspx?id=o#Section_1.

morphine.[78] To convert milligrams of oxycodone to MME, the CDC's published conversion rate is 1.5 – *i.e.*, the smallest OxyContin tablet sold by Purdue, a single 10-milligram tablet, is equivalent to 15 MME, while the largest 80-milligram tablet is equivalent to 120 MME.

204. When prescribing opioids, the CDC recommends that physicians take "extra precautions" at the level of 50 or more MME per day, which the CDC says increases the risks of overdose by at least 2 times the overdose risk present at doses of less than 20 MME per day. Further, the CDC recommends avoiding increasing a patient's opioid dosage to 90 or more MME per day.

205. Using the CDC's guidelines, assuming that doctors prescribe only the smallest OxyContin 10-milligram tablets, it would take only 6 tablets per day to equal 90 MME per day, the level which the CDC ***recommends avoiding***. It would take only 3.5 tablets per day to exceed the CDC's "extra precaution" level of 50 MME. And if a person were to move up from the 10-milligram tablet to the 20-milligram OxyContin tablet, he or she would only need 2 tablets per day to ingest 60 MME, well in excess of the CDC's "extra precaution" level. When the 80-milligram OxyContin tablet is distributed with a 120 MME value, an individual taking just one of these tablets per day far exceeds not only the CDC's 50 MME "extra precaution" level, but also the CDC's 90 MME level it suggests be "avoided."

206. Of the 97,068,585 and 87,234,447 total prescription opioid dosage units filled in the TJSA in 2015 and 2016, respectively, 24% and 26% of those dosage units were oxycodone.[79]

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[78] *See* CDC, *Calculating Total Daily Dose of Opioids for Safer Dosage*, https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf, (last visited Mar. 7, 2018); *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, (Mar. 15, 2016) https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

[79] Calculated based upon the number of oxycodone dosage units divided by the number of Cherokee Nation citizens divided by 365 days for each year, assuming 3.5 10-milligram tablet doses per day.

207. It is extremely unlikely that all or most of the opioid doses sold were of the smallest 10-milligram size. In a 2014 analysis by the University of Arkansas School for Medical Sciences, on behalf of the *L.A. Times*, scientists analyzed OxyContin prescriptions in an insurance claims database covering approximately 7 million individuals across the United States. The scientists found that more than 52% of the individuals taking OxyContin for longer than three months were prescribed doses greater than 60 milligrams per day. 60 milligrams of OxyContin is equal to 90 MME – the range which the CDC recommends avoiding.

208. The following statistics regarding the amount of opioids shipped into each of the 14 counties in the TJSA further underscores the opioid manufacturers' disregard for the welfare of the Cherokee Nation citizens:[80]

County	Total 2015-2016 Opioid Dosage Units	2016 Adult Population	Opioid Dosage Units Per Adult
Muskogee	14,443,308	52,455	275
McIntosh	4,335,420	15,871	273
Cherokee	9,957,480	37,743	264
Mayes	7,999,038	31,099	257
Sequoyah	7,117,463	31,590	227
Wagoner	12,842,308	58,337	220
Craig	2,495,341	11,378	219
Rogers	14,034,880	69,742	201
Washington	7,828,168	39,847	196
Ottawa	4,625,958	23,768	195
Tulsa	89,935,177	478,990	188
Nowata	1,504,139	8,075	186
Adair	2,949,482	16,176	182
Delaware	4,198,798	32,070	131

[80] Values for the Total 2015-2016 Opioid Dosage Units were obtained from the PMP; values for the 2016 Total Population were obtained from the U.S. Census Bureau; values for the 2016 Adult Population were calculated using the U.S. Census Bureau data for the population of each county and the U.S. Census Bureau's 2016 estimate of each county's population that was over the age of 18; and values for the Opioid Dosage Units Per Adult were calculated by dividing the Total 2015-2016 Opioid Dosage Units by the 2016 Adult Population.

Total - 14 Counties	184,267,032	907,141	203

209. Defendants have spent decades misleading physicians about the dangers of opioids. As a result, as illustrated by the statistics above, physicians in and around the Cherokee Nation routinely overprescribe dangerous, highly addictive drugs to their patients.

210. Examples abound. Mark Rogow, M.D., a general practitioner located in Roland, Oklahoma, prescribed opioids to 76% of his patients in 2015. The average percentage of patients filling an opioid prescription for general practitioners in Oklahoma is 35%. Similarly, physician assistant Craig Alpaugh of Tahlequah – the capital of the Cherokee Nation – prescribed opioids to 71% of his patients. Yet prescribers within the same specialty prescribed opioids to only 11% of their patients, a rate that Alpaugh exceeded by about 545%. Neither Rogow nor Alpaugh are outliers. Among all providers in Tahlequah who wrote 50 or more prescriptions, every single provider wrote opioid prescriptions more often than the average in-state specialist in their field.

211. That group includes a number of general or family physicians. Yinyin Devoe, M.D., a family practitioner in Tulsa, prescribed opioids to 96% of her patients. The average family practitioner in Oklahoma prescribed opioids to only 26% of their patients. Dr. Devoe exceeded this rate by approximately 269%. Likewise, 90% of Christopher Moses, D.O.'s 229 patients filled at least one prescription for an opioid, compared to an average of 26% among other family physicians in Oklahoma.

212. Purdue has interacted with the vast majority of Oklahoma physicians who prescribed opioids, including OxyContin. Daniel Morris, D.O., of Broken Arrow, Oklahoma, was paid $33,322.37 by Purdue in 2016, well above the national mean of $3,273.71. Dr. Morris prescribed opioids to 92% of his patients. OxyContin was Dr. Morris' third most prescribed drug.

213. The impact of the epidemic on Indian country has been devastating. In 2016, the former U.S. Surgeon General visited with tribal representatives in Oklahoma and declared that the "prescription opioid abuse epidemic that is sweeping across the U.S. has hit Indian country particularly hard." The impact on young Cherokee Nation citizens in Oklahoma has been the hardest of all. By 12th grade, nearly 13% of American Indian teens living on reservations have used OxyContin. The use of OxyContin by American Indian 12th-graders was about double the national average.

214. Similarly, a 2014 study funded by the National Institute on Drug Abuse found a much higher prevalence of drug and alcohol use in American Indian 8th and 10th graders compared with national averages. American Indian students' annual heroin and OxyContin use was about two to three times higher than the national averages in those years.[81]

215. The fact that American Indian teens, including Cherokee Nation children, are able to easily obtain opioids at these alarming rates indicates the degree to which the pervasive marketing of opioids over the last 20 years has been successful and the resulting widespread diversion of opioid drugs. Defendants' marketing misled physicians and patients, causing physicians to broadly prescribe opioids and patients to request opioids for all types of aches and pains – opioids that are then diverted for non-medical purposes, such as abuse by Cherokee Nation teens.

216. Sadly, even the Cherokee Nation's youngest citizens – its newborn infants – bear the consequences of the opioid abuse epidemic fueled in part by Defendants' conduct. Many Cherokee women become addicted to prescription opioids based upon the deceptive and untrue marketing claims about opioids, and they end up using these drugs during their pregnancies. As

[81] Linda R. Stanley et al., *Rates of Substance Abuse of American Indian Students in 8th, 10th, and 12th Grades Living on or Near Reservations: Update, 2009-2012*, 129 PUB. HEALTH REP. 156, 156-63 (Mar.-Apr. 2014).

a result, many Cherokee infants are born addicted to prescription opioids and suffer from opioid withdrawal and Neonatal Abstinence Syndrome.

217. Neonatal Abstinence Syndrome babies are immediately separated from their families and placed into the custody of the Cherokee Nation Indian Child Welfare ("ICW"), or receive Cherokee Nation governmental services so that they can be afforded medical treatment and be protected from their drug-addicted mothers (and, in many cases, their drug-addicted fathers, too).

218. Pregnant American Indian women are up to 8.7 times more likely to be diagnosed with opioid dependency or abuse compared to the next highest race/ethnicity. In some communities upwards of 1 in 10 pregnant American Indian women have a diagnosis of opioid dependency or abuse. Upon information and belief, these statistics apply similarly to pregnant women who are Cherokee citizens or the mothers of Cherokee children.[82]

219. Defendants' unfair and deceptive marketing of opioids and failure to prevent opioid diversion in and around the Cherokee Nation contribute to a range of social problems, including violence, delinquency, and mortality through the over-prescription of opioid drugs for improper medical conditions. Adverse social outcomes include child abuse and neglect, family dysfunction, criminal behavior, poverty, property damage, unemployment, and social despair.[83] As a result, more and more Cherokee Nation resources are devoted to addiction-related problems, leaving a diminished pool of resources available to devote to positive societal causes

[82] Minn. Dep't of Human Servs., Presentation at the Children's Justice Initiative Conference, *Maternal Opiate Use and Opiate-Affected Newborns* (Sept. 28, 2015).

[83] A study released in March 2018 by the American Action Forum revealed that in 2015, almost one million people between the ages of 25 and 54 were not working because they were dependent on opioid drugs, and that number had grown every year between 1999 and 2015. Ben Gitis & Isabel Soto, *The Labor Force And Output Consequences Of The Opioid Crisis*, American Action Forum (Mar. 27, 2018), https://www.americanactionforum.org/research/labor-force-output-consequences- opioid-crisis/.

like education, cultural preservation, and social programs. Meanwhile, the prescription opioid crisis diminishes the Cherokee Nation's available workforce, decreases productivity, increases poverty, and consequently requires greater government assistance expenditures by the Cherokee Nation.

220. Cherokee Nation society is saturated with highly addictive opioid painkillers as a result of Defendants' lengthy and deceptive opioids marketing campaign and failure to prevent opioid diversion. This ensures that Cherokee Nation citizens will continue to suffer from addiction rates higher than national averages and that Defendants will continue to profit by deceptively marketing, selling, and distributing addictive opioid drugs. This civil lawsuit is the Cherokee Nation's only remaining weapon to hold Defendants liable for the opioid abuse epidemic that they have caused in the Cherokee Nation.

VI. Liability of Defendants

a. False and Deceptive Opioid Marketing

221. Defendants have a duty to exercise reasonable care in their marketing, promotion, and sale of opioids. This involves a duty not to create a foreseeable risk of harm to others. Moreover, one who engages in affirmative conduct – and thereafter realizes or should realize that such conduct has created an unreasonable risk of harm to another – is under a duty to exercise reasonable care to prevent the threatened harm.

222. In addition to having common law duties, Defendants, as manufacturers and marketers of opioids, are governed by the statutory requirements of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, and its implementing regulations. These requirements were enacted to protect society from the harms of drugs that are improperly labeled and marketed. Defendants' violation of these requirements shows that they failed to meet the relevant standard of conduct that society expects.

223. The Federal Food, Drug, and Cosmetic Act prohibits the introduction into interstate commerce of any drug that is misbranded. 21 U.S.C. § 331(a). Pursuant to the statute and case law interpreting the statute, a drug manufacturer can be liable for "misbranding" if its drug labeling is false or misleading in any particular manner. "Labeling" is broadly defined to include not only the label on the product itself but also other written, printed, or graphic matter and advertising regarding the drug.

224. When considering whether a drug under the Federal Food, Drug, and Cosmetic Act is misbranded because the labeling or advertising is misleading, it is not only the content and representations that are made or suggested that must be considered, but also the extent to which "the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the [product]." 21 U.S.C. § 321(n). Defendants have consistently and repeatedly failed to include material facts and representations about the risks and dangers of opioid products in their advertising.

225. By violating the Federal Food, Drug, and Cosmetic Act, Defendants are also liable to Cherokee Nation under the Cherokee Nation Unfair and Deceptive Trade Practices Act ("CNUDPA"). The CNUDPA makes it a civil offense to violate federal statutes affecting or impacting chattels bought for medical purposes, and for making statements concerning the products which are untrue or misleading, which fail to adequately warn, or which are known, or which by the exercise of reasonable care should be known, to be untrue or misleading.

226. The problems engendered by the deceptive and unfair marketing of opioids have been widely publicized for years and were specifically known by Defendants. Defendants themselves paid a significant penalty to the federal government in 2007 for their misstatements in promoting and marketing opioid products. Numerous publications, studies, federal agencies,

and professional organizations have highlighted the epidemic rate of opioid abuse and overdose in Oklahoma communities, including in Indian country, as well as throughout the United States.

227. Defendants have recognized the magnitude of the problem and, at least rhetorically, their legal responsibilities to market and promote opioid products in a more truthful manner. They have made statements assuring the public they are taking steps to curb the opioid epidemic. They have at various times in the past settled claims of improper and deceptive marketing of opioids with the U.S. federal government, the State of Kentucky, and the State of New York, along with a multi-state settlement with more than 25 states in 2007.[84]

228. As part of these settlements, Defendants have voluntarily agreed to cease their deceptive marketing practices.

229. More recently, Purdue has made a last-ditch attempt to avoid liability by halting the marketing of opioid drugs to doctors. This apparent admission of wrongdoing and culpability for the opioid crisis is too little, too late.[85]

230. Thus, in addition to the obligations imposed by law, through their own words and actions, Defendants have voluntarily undertaken a duty to protect the public at large against deceptive marketing claims to curb the opioid epidemic.

231. Yet, Defendants have continued to promote, directly and indirectly, deceptive marketing messages that fail to highlight the risks and dangers of opioid usage in and around the Cherokee Nation, with the actual or constructive knowledge that the opioids were ultimately being consumed by Cherokee Nation citizens for non-medical purposes.

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[84] *See, e.g.*, Shannon Henson, *Purdue Pharma Settles with States Over Oxycontin*, Law360 (May 8, 2007), https://www.law360.com/articles/24311/purdue-pharma-settles-with-states-over-oxycontin.

[85] *See* Matt Perrone, *OxyContin Maker Purdue to Stop Promoting Opioids to Doctors, Cut Half of Sales Staff*, Chi. Trib. (Feb. 10, 2018), *available at* http://www.chicagotribune.com/business/ct-purdue-opioids-20180210-story.html.

232. The Defendants negligently or intentionally failed to adequately control the content and distribution of marketing materials and sales efforts of their opioid products. A reasonably prudent manufacturer of Schedule II controlled substances would have anticipated the dangers of widely advertising and distributing dangerous opioid products, and protected against them. It could have, for example, ensured physicians were cautious and judicious in considering whether to prescribe opioids; carefully worded its marketing materials to ensure the dangers and risks of opioids were clearly communicated; conducted and publicized scientific studies that test both the efficacy and potential dangers of opioid products; taken greater care in hiring, training, and supervising employees that are responsible for marketing and selling opioid products; investigated demographic or epidemiological facts concerning the increasing demand for narcotic painkillers in and around the Cherokee Nation and the linkage of that demand with Defendants' marketing efforts; and, in general, simply followed applicable statutes, regulations, professional standards, and guidance from government agencies and the terms of prior settlements that Defendants have agreed to. Defendants did none of those things.

233. Defendants have now, under pressure from multiple state attorneys general and others, made some small efforts to rein in their decades-long efforts to increase sales of opioids to physicians. That does not erase the damage that has been done to date.

234. It was reasonably foreseeable to Defendants that their deceptive and aggressive marketing of opioid drugs in and around the Cherokee Nation would allow opioids to fall into the hands of children, addicts, criminals, and other unintended users due to the over-prescribing of opioids for many forms of chronic pain.

235. It was reasonably foreseeable to Defendants that tragic, preventable injuries – including abuse, addiction, overdoses, and death – would result when unintended users gained

access to opioids based on deceptive and false marketing. It was also reasonably foreseeable that many of these injuries would be suffered by Cherokee Nation citizens, and that the costs of these injuries would be shouldered by the Cherokee Nation.

236. The Defendants knew or should have known that their continuing efforts to employ deceptive and unfair marketing, despite being previously sanctioned by other federal and state officials, would contribute to the Cherokee Nation's opioid epidemic, and would create access to opioids by unauthorized users, which, in turn, would perpetuate the cycle of abuse, addiction, demand, and illegal transactions.

237. The Defendants knew or should have known that a substantial amount of the opioids dispensed in and around the Cherokee Nation were being dispensed as a result of Defendants' deceptive and unfair marketing. It was foreseeable that the increased number of prescriptions for opioids resulting from Defendants' deceptive and unfair marketing would cause harm to individual pharmacy customers, third parties, and the Cherokee Nation.

238. The Defendants were aware of widespread prescription opioid abuse in and around the Cherokee Nation, but they nevertheless persisted in a pattern of marketing, advertising, and distributing opioids in those geographic areas.

239. The Defendants made substantial profits over the years based on the deceptive and unfair marketing of opioids in the Cherokee Nation. Their participation and cooperation in a common enterprise has foreseeably caused injuries to the citizens of the Cherokee Nation and financial damages to the Cherokee Nation. The Defendants knew full well that the Cherokee Nation would be unjustly forced to bear the costs of these injuries and damages.

240. The Defendants' intentional deceptive and unfair marketing of prescription opioids to relatively small communities primarily serving Cherokee Nation citizens showed an

intentional or reckless disregard for the safety of the Cherokee Nation and its citizens. Their conduct poses a continuing threat to the health, safety, and welfare of the Cherokee Nation.

b. Opioid Diversion

241. In addition to having created an environment ripe for opioid over-prescription and abuse through illegal marketing, Defendants have common law duties in connection with their prominent role in the supply chain of opioid products. In particular, Defendants have a duty to exercise reasonable care under the circumstances in their capacity as manufacturers and distributors of opioids. This involves a duty not to create a foreseeable risk of harm to others – something they have repeatedly overlooked by failing to address opioid diversion and failing to maintain control over their opioid manufacturing and distributing operations despite having the granular data to address and prevent the risk of harm to the Cherokee Nation. Additionally, one who engages in affirmative conduct – and thereafter realizes or should realize that such conduct has created an unreasonable risk of harm to another – is under a duty to exercise reasonable care to prevent the threatened harm.

242. In addition to common law duties to prevent foreseeable harm through the improper shipments and diversion of opioids, Defendants, as manufacturers and distributors of opioids, are governed by the statutory requirements of the CSA, 21 U.S.C. §§ 801 *et seq.*, and its implementing regulations. These requirements were enacted to protect society from the harms of drug diversion. Defendants' violation of these statutory requirements shows that they failed to meet the relevant standard of conduct that society expects.

243. By violating the CSA, Defendants are also liable to the Cherokee Nation under the Cherokee Nation Unfair and Deceptive Trade Practices Act, which specifically makes it a civil offense to violate federal statutes affecting or impacting chattels bought for medical purposes.

244. Manufacturers and distributors have themselves recognized the magnitude of the problem and, at least rhetorically, their legal responsibilities to prevent diversion. They have made statements assuring the public they are supposedly undertaking a duty to curb the opioid epidemic. These include statements on Purdue's website, such as, "Purdue's industry-leading Abuse & Diversion Detection (ADD) program, launched in 2002 and publicly disclosed in 2003, is one of several Purdue initiatives designed to help address our nation's opioid epidemic . . . . Our procedures help ensure that whenever we observe potential abuse or diversion activity, we discontinue our company's interaction with the prescriber or pharmacist and initiate an investigation."[86]

245. Thus, in addition to the obligations imposed by law, through their own words and actions, Defendants have voluntarily undertaken a duty to protect the public at large against diversion from their supply chains, and to curb the opioid epidemic. And notably, from Purdue's own statement above, Defendants have access to data, such as ARCOS data, that allows them to track the opioids they produce all the way down to the prescriber or pharmacist level.

246. Nevertheless, Defendants have supplied quantities of prescription opioids in and around the Cherokee Nation with the actual or constructive knowledge that the opioids were ultimately being consumed by Cherokee Nation citizens for non-medical purposes. Many of these shipments should have been stopped or investigated as suspicious orders, but Defendants negligently or intentionally failed to do so.

[86] Purdue Pharma, *Setting the Record Straight on Our Anti-Diversion Programs* (July 11, 2016) http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/.

247. Defendants knew or should have known that the amount of opioids that they allowed to flow into the Cherokee Nation was far in excess of what could be consumed for medically necessary purposes in the relevant communities.

248. Defendants negligently or intentionally failed to adequately control their supply lines to prevent diversion. A reasonably prudent manufacturer and distributor of Schedule II controlled substances would have anticipated the danger of opioid diversion and protected against it by, for example, taking greater care in hiring, training, and supervising employees; providing greater oversight, security, and control of supply channels; looking more closely at the pharmacists and doctors who were purchasing large quantities of commonly abused opioids in amounts greater than the populations in those areas would warrant; investigating demographic or epidemiological facts concerning the increasing demand for narcotic painkillers in and around the Cherokee Nation; providing information to pharmacies and retailers about opioid diversion; and in general, simply following applicable statutes, regulations, professional standards, and guidance from government agencies.

249. On information and belief, Defendants made little to no effort to investigate or visit the distributors and pharmacies servicing the Cherokee Nation to perform due diligence inspections to ensure that the controlled substances Defendants had furnished were not being diverted to illegal uses.

250. It was reasonably foreseeable to Defendants that their conduct in flooding the market in and around the Cherokee Nation with highly addictive opioids would allow opioids to fall into the hands of children, addicts, criminals, and other unintended users.

251. It was reasonably foreseeable to Defendants that tragic, preventable injuries – including addiction, overdoses, and death – would occur when unintended users gained access to

opioids. It is also reasonably foreseeable that many of these injuries will be suffered by Cherokee Nation citizens and that the costs of these injuries would be shouldered by the Cherokee Nation.

252. Defendants knew or should have known that the opioids being diverted from their supply chains would contribute to the Cherokee Nation opioid epidemic, and would create access to opioids by unauthorized users, which, in turn, perpetuated the cycle of addiction, demand, and illegal transactions.

253. Defendants knew or should have known that a substantial amount of the opioids dispensed in and around the Cherokee Nation were being dispensed based on invalid or suspicious prescriptions. It was foreseeable that filling suspicious orders for opioids will cause harm to individual pharmacy customers, third parties, and the Cherokee Nation.

254. Defendants were aware of widespread prescription opioid abuse and diversion in and around the Cherokee Nation, but nevertheless persisted in a pattern of distributing commonly abused and diverted opioids in geographic areas – and in such quantities, and with such frequency – that Defendants knew or should have known these commonly abused controlled substances were not being distributed for legitimate medical purposes.

255. The use of opioids by Cherokee Nation citizens who were addicted or who did not have a medically necessary purpose could not occur without the knowing cooperation and assistance of Defendants. If Defendants adhered to effective controls to guard against diversion, the Cherokee Nation and its citizens would have avoided significant injury.

256. Defendants made substantial profits over the years based on the diversion of opioids into the Cherokee Nation. Their participation and cooperation in a common enterprise has foreseeably caused injuries to the citizens of the Cherokee Nation and financial damages to

the Cherokee Nation. Defendants knew full well that the Cherokee Nation would be unjustly forced to bear the costs of these injuries and damages.

257. Defendants' intentional manufacture and distribution of excessive amounts of prescription opioids to relatively small communities primarily serving Cherokee Nation citizens showed an intentional or reckless disregard for the safety of the Cherokee Nation and its citizens. Their conduct poses a continuing threat to the health, safety, and welfare of the Cherokee Nation.

VII. The Individual Defendants Led Purdue's Misconduct

258. This section of the Complaint identifies the individuals who are personally responsible for Purdue's illegal scheme. Cherokee Nation law against unfair and deceptive conduct in commerce applies to individuals regardless of whether they are officers, directors, or employees. Holding individuals personally liable for their misconduct does not require piercing a corporate veil. In this case, the individual defendants made the decisions to break the law; they controlled the unfair and deceptive conduct; and they personally collected millions of dollars from that deception.

Summary of The Individual Defendants' Misconduct

259. The individual defendants were the chief architects and beneficiaries of Purdue's deception. In summary:

260. The individual defendants controlled the misconduct described in paragraphs 1-256 above.

261. Each individual defendant knowingly and intentionally sent sales reps to promote opioids to prescribers in Oklahoma and the TJSA thousands of times.

262. Each individual defendant knew and intended that the sales reps in Oklahoma and the TJSA would unfairly and deceptively promote opioid sales that are risky for patients, including by:

- falsely blaming the dangers of opioids on patients instead of the addictive drugs;
- pushing opioids for elderly patients, without disclosing the higher risks;
- pushing opioids for patients who had never taken them before, without disclosing the higher risks;
- pushing opioids as substitutes for safer medications, with improper comparative claims;
- falsely assuring doctors and patients that reformulated OxyContin was safe;
- pushing doctors and patients to use higher doses of opioids, without disclosing the higher risks;
- pushing doctors and patients to use opioids for longer periods of time, without disclosing the higher risks; and
- pushing opioid prescriptions by doctors that Purdue knew were writing dangerous prescriptions.

263. Each individual defendant knew and intended that the sales reps would not tell Oklahoma and TJSA doctors and patients the truth about Purdue's opioids. Indeed, they knew and intended that these unfair and deceptive tactics were achieving their purpose of concealing the truth.

264. Each individual defendant knew and intended that prescribers, pharmacists, and patients in Oklahoma and the TJSA would rely on Purdue's deceptive sales campaign to prescribe, dispense, and take Purdue opioids. Securing that reliance was the purpose of the marketing campaign.

265. Each individual defendant knew and intended that staff reporting to them would pay top prescribers tens of thousands of dollars to encourage other doctors to write dangerous prescriptions in Oklahoma and the TJSA.

266. Each individual defendant knew and intended that staff reporting to them would take thousands of additional misleading acts in Oklahoma and the TJSA, including by sending

deceptive publications to Oklahoma and the TJSA doctors and deceptively promoting Purdue opioids.

267. Each individual defendant knowingly and intentionally took money from Purdue's deceptive business in Oklahoma and the TJSA.

268. Each individual defendant knowingly and intentionally sought to conceal his or her misconduct.

a. Richard Sackler, Beverly Sackler, David Sackler, Ilene Sackler Lefcourt, Jonathan Sackler, Kathe Sackler, Mortimer Sackler, and Theresa Sackler

269. Eight people in a single family made the choices that caused much of the opioid epidemic. The Sackler family owns Purdue, and they always held a majority of the seats on its Board. Because they controlled their own privately held drug company, the Sacklers had the power to decide how addictive narcotics were sold. They hired hundreds of workers to carry out their wishes, and they fired those who did not sell enough drugs. They got more patients on opioids, at higher doses and for a longer time, than ever before. They paid themselves billions of dollars. They are responsible for the addiction, overdose, and death that has damaged millions of lives. They should be held accountable now.

The Sacklers' Misconduct Leading To The 2007 Massachusetts Judgment

270. The misconduct of Richard, Beverly, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler was particularly unfair, deceptive, unreasonable, and unlawful because they already had been given a second chance. From the 1990s until 2007, they directed a decade of misconduct, which led to criminal convictions, a judgment in the Massachusetts court, and commitments that Purdue would not deceive doctors and patients again. That background confirms that their misconduct since 2007 was knowing and intentional.

271. The Sackler family's first drug company was the Purdue Frederick Company, which they bought in 1952. In 1990, they created Purdue Pharma Inc. and Purdue Pharma L.P. Richard, Beverly, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler took seats on the Board. For events before July 2012, this petition uses "the Sacklers" to refer to them. David Sackler joined the Board in July 2012. From that time forward, "the Sacklers" includes him as well.

272. The Sacklers always insisted that their family control Purdue. From 1990 until today, their family always held the majority of seats on the Board. In 1994, Jonathan Sackler issued a memorandum to Purdue staff requiring that the Sacklers should receive "all Quarterly Reports and any other reports directed to the Board."

273. Purdue launched OxyContin in 1996. It would become one of the deadliest drugs of all time. The FDA scientist who evaluated OxyContin wrote in his original review: "Care should be taken to limit competitive promotion." The Sacklers did not agree. From the beginning, the Sacklers viewed limits on opioids as an obstacle to greater profits. To make more money, the Sacklers considered whether they could sell OxyContin in some countries as an uncontrolled drug. Staff reported to Richard Sackler that selling OxyContin as "non-narcotic," without the safeguards that protect patients from addictive drugs, would provide "a vast increase of the market potential." The inventor of OxyContin, Robert Kaiko, wrote to Richard to oppose this dangerous idea. Kaiko wrote that he was "very concerned" about the danger of selling OxyContin without strict controls. Kaiko warned: "I don't believe we have a sufficiently strong case to argue that OxyContin has minimal or no abuse liability." To the contrary, Kaiko wrote, "oxycodone containing products are still among the most abused opioids in the U.S." Kaiko predicted: "If OxyContin is uncontrolled, . . . it is highly likely that it will eventually be abused." Richard responded: "How substantially would it improve your sales?"

274. At the OxyContin launch party, Richard Sackler spoke as the Senior Vice President responsible for sales. He asked the audience to imagine a series of natural disasters: an earthquake, a volcanic eruption, a hurricane, and a blizzard. He said that "the launch of OxyContin Tablets will be followed by a blizzard of prescriptions that will bury the competition. The prescription blizzard will be so deep, dense, and white. . . ." Over the next twenty years, the Sacklers made Richard's boast come true. They created a manmade disaster. Their blizzard of dangerous prescriptions buried children, parents, and grandparents across Oklahoma and the TJSA, and the burials continue.

275. From the beginning, the Sacklers were behind Purdue's decision to deceive doctors and patients. In 1997, Richard Sackler, Kathe Sackler, and other Purdue executives determined – and recorded in internal correspondence — that doctors had the crucial misconception that OxyContin was weaker than morphine, which led them to prescribe OxyContin much more often, even as a substitute for Tylenol. In fact, OxyContin is more potent than morphine. Richard directed Purdue staff not to tell doctors the truth, because the truth could reduce OxyContin sales.

276. From the start, the Sacklers were also the driving force behind Purdue's strategy to push opioids with the false promise that they create an enhanced "lifestyle." In 1998, Richard Sackler instructed Purdue's executives that OxyContin tablets provide more than merely "therapeutic" value and instead "enhance personal performance," like Viagra.

277. Most of all, the Sacklers cared about money. Millions of dollars were not enough. They wanted billions. They cared more about money than about patients, or their employees, or the truth. In 1999, when employee Michael Friedman reported to Richard Sackler that Purdue was making more than $20,000,000 per week, Richard replied immediately, at midnight, that the sales were "not so great." "After all, if we are to do 900M this year, we should be running at

75M/month. So it looks like this month could be 80 or 90M. Blah, humbug. Yawn. Where was I?"

278. In 1999, Richard Sackler became the CEO of Purdue. Jonathan, Kathe, and Mortimer were Vice Presidents. The company hired hundreds of sales representatives and taught them false claims to use to sell drugs. Purdue managers tested the sales reps on the most important false statements during training at company headquarters. On the crucial issue of addiction, which would damage so many lives, Purdue trained its sales reps to deceive doctors that the risk of addiction was "less than one percent." Purdue mailed thousands of doctors promotional videos with that same false claim:

> There's no question that our best, strongest pain medicines are the opioids. But these are the same drugs that have a reputation for causing addiction and other terrible things. Now, in fact, the rate of addiction amongst pain patients who are treated by doctors is much less than one percent. They don't wear out, they go on working, they do not have serious medical side effects.

279. A sales rep told a reporter: "We were directed to lie. Why mince words about it? Greed took hold and overruled everything. They saw that potential for billions of dollars and just went after it."

280. In 2000, the Sacklers were warned that a reporter was "sniffing about the OxyContin abuse story." The Sackler family put the threat on the agenda for the next Board meeting and began covering their tracks. They planned a response that "deflects attention away from the company owners."

281. In January 2001, Richard Sackler received a plea for help from a Purdue sales representative. The sales rep described a community meeting at a local high school, organized by mothers whose children overdosed on OxyContin and died. "Statements were made that

OxyContin sales were at the expense of dead children and the only difference between heroin and OxyContin is that you can get OxyContin from a doctor."

282. The next month, a federal prosecutor reported 59 deaths from OxyContin in a single state. The Sacklers knew that the reports underestimated the destruction. Richard Sackler wrote to Purdue executives: "This is not too bad. It could have been far worse." The next week, on February 14, a mother wrote a letter to Purdue:

> My son was only 28 years old when he died from Oxycontin on New Year's Day. We all miss him very much, his wife especially on Valentines' Day. Why would a company make a product that strong (80 and 160 mg) when they know they will kill young people? My son had a bad back and could have taken Motrin but his Dr. started him on Vicodin, then Oxycontin then Oxycontin SR. Now he is dead!

A Purdue staff member noted: "I see a liability issue here. Any suggestions?"

283. That same month, Richard Sackler wrote down his solution to the overwhelming evidence of overdose and death: blame and stigmatize people who become addicted to opioids. Sackler wrote in a confidential email: "We have to hammer on the abusers in every way possible. They are the culprits and the problem. They are reckless criminals." Richard followed that strategy for the rest of his career: collect millions from selling addictive drugs, and blame the terrible consequences on the people who became addicted.

284. For example, in an email exchange discussing whether people dependent on opioids "want to be addicts" Richard Sackler wrote: "I'll tell you something that will totally revise your belief that addicts don't want to be addicted. It is factually untrue. They get themselves addicted over and over again." Richard reiterated his point: "[Opioid addicts] are criminals, and they engage in it with full, criminal intent. Why should they be entitled to our sympathies?" He further wrote: "This vilification is shit."

285. Rather than be concerned with the thousands impacted by opioid addiction, Richard Sackler expressed concern only over his and Purdue's "vilification."

286. By their misconduct, the Sacklers have hammered Oklahoma and the TJSA families in every way possible. And the stigma they used as a weapon made the crisis even worse.

287. Not long after the mother's February 14 letter, the Sacklers achieved a long-sought goal. The front page of the *New York Times* reported that "OxyContin's sales have hit $1 billion, more than even Viagra's." The same article noted that "OxyContin has been a factor in the deaths of at least 120 people, and medical examiners are still counting."

288. When *Time* published an article about OxyContin deaths, Purdue employees told Richard Sackler they were concerned. Richard responded with a message to his staff. He wrote that *Time*'s coverage of people who lost their lives to OxyContin was not "balanced," and the deaths were the fault of "the drug addicts," instead of Purdue. "We intend to stay the course and speak out for people in pain – who far outnumber the drug addicts abusing our product."

289. That spring, Purdue executives met with the U.S. DEA. A senior DEA official sat across from Richard Sackler. Before the meeting ended, she leaned over the table and told Richard: "People are dying. Do you understand that?"

290. As Purdue kept pushing opioids and people kept dying, the company was engulfed in a wave of investigations by state attorneys general, the DEA, and the DOJ. In 2003, Richard Sackler left his position as President of Purdue. After a few more years of investigation, Jonathan, Kathe, and Mortimer Sackler resigned from their positions as Vice Presidents. But those moves were for show. The Sacklers kept control of the company. Their family owned Purdue. They controlled the Board. They paid themselves the profits. And, as alleged in detail below, they continued to direct Purdue's deceptive marketing campaign.

291. By 2006, prosecutors found damning evidence that Purdue intentionally deceived doctors and patients about its opioids. The Sacklers voted that their first drug company, the Purdue Frederick Company, should plead guilty to a felony for misbranding OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause adverse events and side effects than other pain medications. The Sacklers also voted on the Board that decided that three Purdue executives (Michael Friedman, Paul Goldenheim, and Howard Udell) – but no member of the Sackler family – should plead guilty as individuals.

292. In May 2007, the Sacklers voted again to have Purdue Frederick Company plead guilty and enter a series of agreements that Purdue would never deceive doctors and patients about opioids again. The Purdue Frederick Company confessed to a felony and effectively went out of business. The Sacklers continued their opioid business in two other companies: Purdue Pharma Inc. and Purdue Pharma L.P.

293. In an Agreed Statement Of Facts, the Sacklers voted to admit that, for more than six years, supervisors and employees *intentionally* deceived doctors about OxyContin: "Beginning on or about December 12, 1995, and continuing until on or about June 30, 2000, certain Purdue supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications."

294. To remove any doubt, the Sacklers voted to enter into a plea agreement that stated: "Purdue is pleading guilty as described above because Purdue is in fact guilty." Those intentional violations of the law happened while Richard Sackler was CEO; Jonathan, Kathe, and Mortimer were Vice Presidents; and Richard, Jonathan, Kathe, Mortimer, Ilene, Beverly, and Theresa Sackler were all on the Board.

295. The Sacklers also voted for Purdue to enter a Corporate Integrity Agreement with the U.S. government. The agreement required the Sacklers to ensure that Purdue did not deceive doctors and patients again. The Sacklers promised to comply with rules that prohibit deception about Purdue opioids. They were required to complete hours of training to ensure that they understood the rules. They were required to report any deception. Richard, Beverly, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler each certified in writing to the government that he or she had read and understood the rules and would obey them.

296. Finally, the Sacklers voted to enter into a Consent Judgment in Massachusetts Superior Court ("2007 Massachusetts Judgment"). The 2007 Massachusetts Judgment ordered that Purdue "shall not make any written or oral claim that is false, misleading, or deceptive" in the promotion or marketing of OxyContin. The judgment further required that Purdue provide fair balance regarding risks and benefits in all promotion of OxyContin. That judgment required fair balance about the risks of taking higher doses for longer periods and the risks of addiction, overdose, and death.

297. The 2007 Massachusetts Judgment further required that Purdue establish and follow an abuse and diversion detection program to identify high-prescribing doctors who show signs of inappropriate prescribing, stop promoting drugs to them, and report them to the authorities:

> "Upon identification of potential abuse or diversion," Purdue must conduct an inquiry and take appropriate action, "which may include ceasing to promote Purdue products to the particular Health Care Professional, providing further education to the Health Care Professional about appropriate use of opioids, or providing notice of such potential abuse or diversion to appropriate medical, regulatory or law enforcement authorities."

298. The 2007 Massachusetts Judgment and related agreements should have ended the Sacklers' misconduct for good. Instead, the Sacklers decided to break the law again and again,

expanding their deceptive sales campaign to make more money from more patients on more dangerous doses of opioids.

The Sacklers' Misconduct From The 2007 Massachusetts Judgment Until Today

299. From the 2007 Massachusetts Judgment to 2018, the Sacklers controlled Purdue's deceptive sales campaign. They directed the company to hire hundreds more sales reps to visit doctors thousands more times. They insisted that sales reps repeatedly visit the most prolific prescribers. They directed reps to encourage doctors to prescribe more of the highest doses of opioids. They studied unlawful tactics to keep patients on opioids longer and then ordered staff to use them. They asked for detailed reports about doctors suspected of misconduct, how much money Purdue made from them, and how few of them Purdue had reported to the authorities. They sometimes demanded more detail than anyone else in the entire company, so staff had to create special reports just for them. Richard Sackler even went into the field to promote opioids to doctors and to supervise reps face to face.

300. The Sacklers' micromanagement was so intrusive that staff begged for relief. The Vice President of Sales and Marketing wrote to the CEO: "Anything you can do to reduce the direct contact of Richard into the organization is appreciated."

301. The Sacklers' directions shot through the company with dangerous force. When the Sacklers berated sales managers, the managers turned around and fired straight at reps in the field.

302. The Sacklers cared most of all about money. From 2007 to 2018, they voted to direct Purdue to pay their family ***billions*** of dollars. These payments show the total control that the Sacklers exercised over Purdue. The payments were the motivation for the Sacklers' misconduct. And the payments were deliberate decisions to benefit from deception in Oklahoma and the TJSA, at great cost to patients and families.

303. As detailed below, the Sacklers' misconduct continued from the 2007 convictions through 2018.

✣ ✣ ✣ ***2007*** ✣ ✣ ✣

304. **In July 2007**, staff told the Sacklers that more than 5,000 cases of adverse events had been reported to Purdue in just the first three months of 2007. Staff also told the Sacklers that Purdue received 572 Reports of Concern about abuse and diversion of Purdue opioids during Q2 2007. Staff reported to the Sacklers that they completed only 21 field inquiries in response. Staff also told the Sacklers that they received more than 100 calls to Purdue's compliance hotline during the quarter, which was a "significant increase," but Purdue did not report any of the hotline calls or Reports of Concern to the FDA, DEA, Department of Justice, or state authorities.

305. Purdue's self-interested failure to report abuse and diversion would continue, quarter after quarter, even though the 2007 Massachusetts Judgment required Purdue to report "potential abuse or diversion to appropriate medical, regulatory or law enforcement authorities." Instead of reporting dangerous prescribers, or even directing sales reps to stop visiting them, the Sacklers chose to keep pushing opioids to whoever prescribed the most.

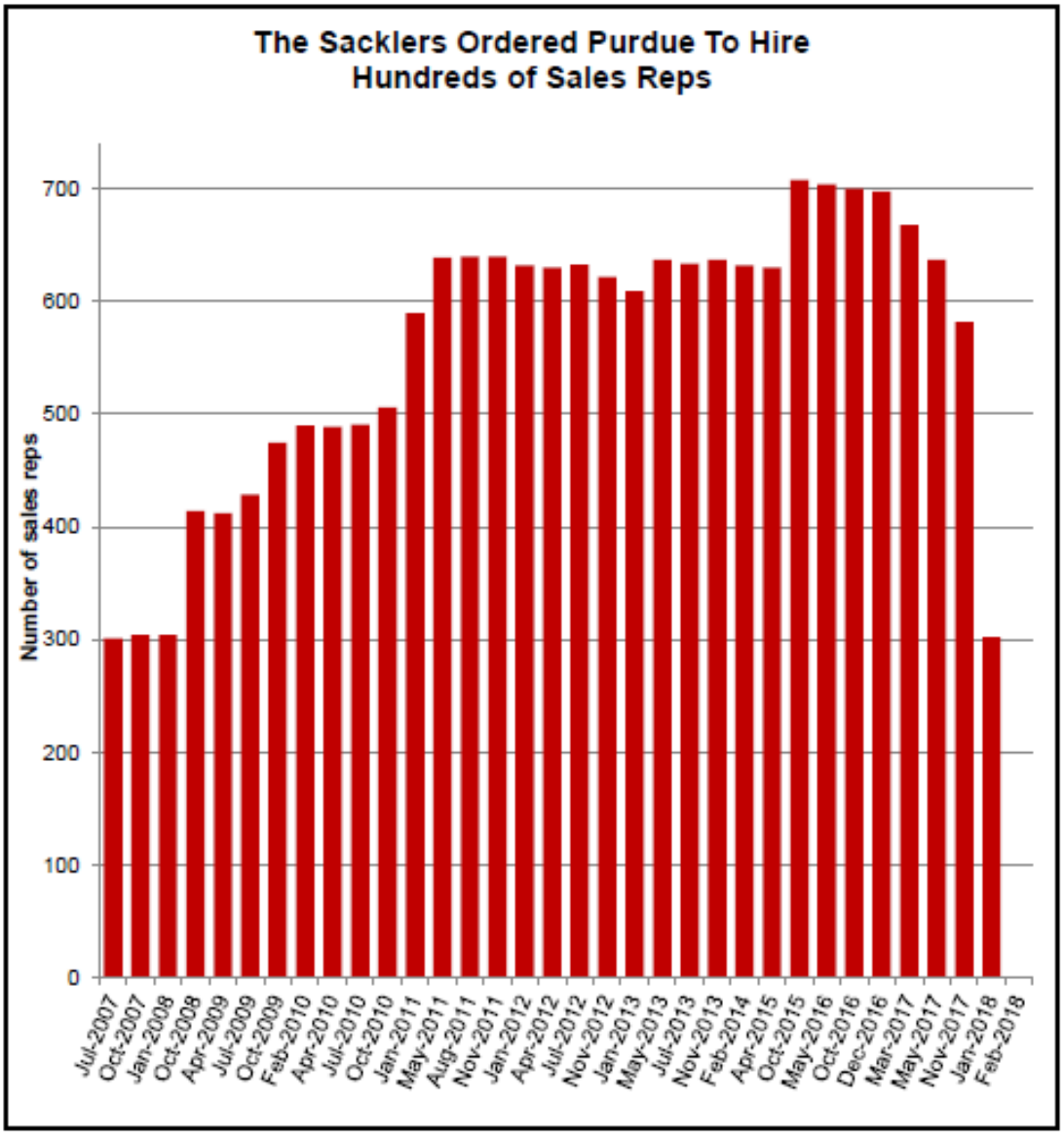
306. Staff also reported to the Sacklers that they continued to mail out thousands of deceptive marketing materials, including 12,528 publications in the first half of 2007. The single most-distributed material was Volume 1 of Purdue's "Focused and Customized Education Topic Selections in Pain Management" ("FACETS"). In FACETS, Purdue falsely instructed doctors and patients that physical dependence on opioids is not dangerous and instead improves patients' "quality of life" – just as Richard Sackler had been saying since the 1990s. In the same material, Purdue also falsely told doctors and patients that signs of addiction are actually "pseudoaddiction," and that doctors should respond by prescribing more opioids. Staff told the

Sacklers that another of the publications they had sent most often to doctors was "*Complexities in Caring for People in Pain*." In it, Purdue repeated again its false claim that warning signs of addiction are really "pseudoaddiction" that should be treated with more opioids.

307. At the same time, staff also reported to the Sacklers that Purdue was making more money than expected. A few months earlier, they had projected a profit of $407,000,000; now they expected more than $600,000,000.

308. Staff reported to the Sacklers that "sales effort" was a key reason that profits were high. Staff told the Sacklers that Purdue employed 301 sales reps to promote opioids and that sales reps were the largest group of Purdue employees by far. In comparison, Purdue employed only 34 people in drug discovery.

309. From the 2007 convictions until today, the Sacklers have ordered Purdue to hire hundreds more sales reps to carry out their deceptive sales campaign.



310. **In August**, Howard Udell was still serving as Purdue's top lawyer, even after his criminal conviction. He wrote to Richard, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler: "Over the last week there have been numerous news stories across the nation reporting on the Associated Press's analysis of DEA data showing very large increases in the use of opioids analgesics (particularly OxyContin) between the years 1997 and 2005. Many of these

articles have suggested that this increase is a negative development suggesting overpromotion and increasing abuse and diversion of these products."

311. **In October**, staff told the Sacklers that Purdue received 284 Reports of Concern about abuse and diversion of Purdue's opioids in Q3 2007, and they conducted only 46 field inquiries in response. Staff reported to the Sacklers that they received 39 tips to Purdue's compliance hotline during the quarter, but Purdue did not report any of them to the authorities.

312. Staff told the Sacklers that Purdue had hired more sales reps and now employed 304. They also reported to the Sacklers that Purdue was succeeding at promoting its highest doses of opioids: "OxyContin 80mg is at Rx levels not seen in over 2 years."

313. In preparation for an upcoming Board meeting, Richard Sackler instructed staff to give him the spreadsheets underlying their sales analysis, so that he could do his own calculations. The spreadsheets showed that, in 2007, Purdue expected to collect more than half its total revenue from sales of 80mg OxyContin – its most powerful, most profitable, and most dangerous pill.

314. **In November**, the Sacklers voted to spend $86,900,000 to employ sales reps in 2008 and another $1,000,000 to buy them laptops. The Sacklers also voted for a resolution regarding salary increases and bonus targets for the reps. Every time the Sacklers voted to spend tens of millions of dollars on sales reps, they knew and intended that they were sending reps to promote opioids in Oklahoma and the TJSA.

✣ ✣ ✣ ***2008*** ✣ ✣ ✣

315. **In January 2008**, staff told the Sacklers that Purdue still employed 304 sales reps and they were succeeding at the goal of promoting higher doses of opioids: "OxyContin 80mg continues to grow." Staff told the Sacklers that, in 2007, Purdue's net sales were just over $1

billion, almost "DOUBLE" what the company had planned. OxyContin was more than 90% of those sales.

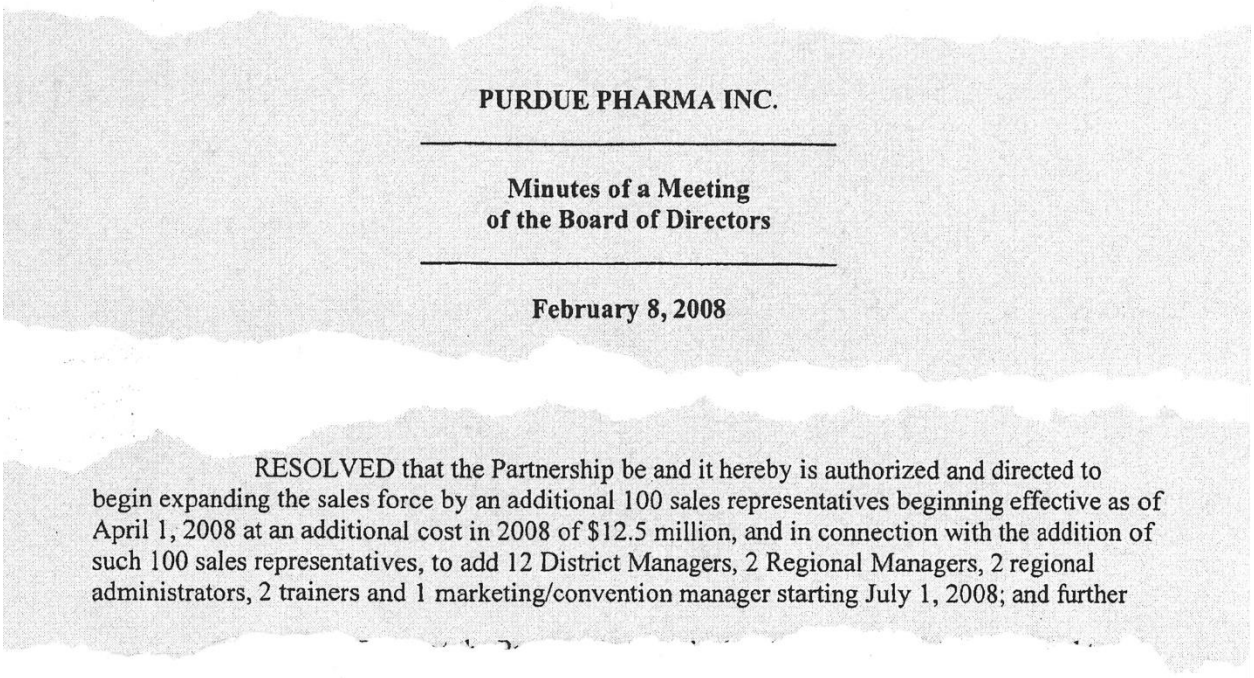
316. Staff also told the Sacklers that Purdue received 689 Reports of Concern about abuse and diversion of Purdue's opioids in Q4 2007, and they conducted only 21 field inquiries in response. Staff also reported to the Sacklers that they received 83 tips to Purdue's compliance hotline during the quarter, but Purdue did not report any of them to the authorities.

317. The Sacklers wanted more details on tactics for pushing sales. Richard Sackler wrote to Russell Gasdia, Vice President of Sales and Marketing (hereinafter "Sales VP"), demanding information about Purdue's opioid savings cards. Richard asked Gasdia how long the opioid savings cards lasted, how much savings they offered a patient, and whether there had been any changes since he had last been briefed on the opioid savings card scheme. Richard sent Gasdia a detailed hypothetical scenario to make sure he understood the sales tactic down to the smallest details. Staff followed up with a presentation about opioid savings cards to the Sacklers at the next Board meeting.

318. Meanwhile, when staff proposed a plan to get pharmacies to increase their inventory of OxyContin from 2 bottles to 3 bottles, Richard Sackler demanded to know why they could not get up to 4 bottles or more.

319. The Sacklers did not only sweat the small stuff. They also made the fundamental decision to hire a sales force, and then to expand it. At Purdue, hiring more sales reps was not a matter for middle management. Selling opioids door-to-door, in visits to doctor's offices and hospitals, was the core business of the company. The Sacklers themselves made the decisions about how big the sales force would be and what it would do.

320. **In February**, the Sacklers used their power on the Board to order Purdue to "begin expanding the sales force by an additional 100 sales representatives beginning effective as of April 1, 2008."



PURDUE PHARMA INC.

Minutes of a Meeting of the Board of Directors

February 8, 2008

RESOLVED that the Partnership be and it hereby is authorized and directed to begin expanding the sales force by an additional 100 sales representatives beginning effective as of April 1, 2008 at an additional cost in 2008 of $12.5 million, and in connection with the addition of such 100 sales representatives, to add 12 District Managers, 2 Regional Managers, 2 regional administrators, 2 trainers and 1 marketing/convention manager starting July 1, 2008; and further

321. The Sacklers also knew and intended that the sales reps would push higher doses of Purdue's opioids. That same month, Richard Sackler directed Purdue management to "measure our performance by Rx's by strength, giving higher measures to higher strengths." He copied Jonathan and Mortimer Sackler on the instruction. The Sacklers knew higher doses put patients at higher risk. As far back as the 1990s, Jonathan and Kathe Sackler knew that patients frequently suffer harm when "high doses of an opioid are used for long periods of time."

322. In February, the Sacklers voted to pay former CEO and criminal convict Michael Friedman $3,000,000. It was one of several multi-million-dollar payments to the convicted executives to maintain their loyalty and protect the Sackler family.

323. By 2008, Purdue was working on a crush-proof reformulation of OxyContin to extend Purdue's patent monopoly. The Sacklers learned that another company was planning

clinical research to test whether crush-proof opioids would be safer for patients. Mortimer Sackler suggested that Purdue conduct similar studies to find out whether reformulated OxyContin was really safer *before* selling it to millions of patients. He wrote to Richard Sackler: "Purdue should be leading the charge on this type of research and should be generating the research to support our formulation. Why are we playing catch up . . . ? Shouldn't we have studies like this . . . ?" The Sacklers decided not to do the research because they wanted the profits from a new product, regardless of whether the deaths continued. Richard didn't want a paper trail, so he instructed Mortimer to call him, and CEO John Stewart met with his staff to plan how to phrase a carefully worded reply. Later that month, Stewart wrote to Richard that reformulating OxyContin "will not stop patients from the simple act of taking too many pills."

324. Meanwhile, staff gave Jonathan, Kathe, Mortimer and Richard Sackler projections indicating that OxyContin sales could plateau. Mortimer demanded answers to a series of questions about why sales would not grow. Richard chimed in at 8:30 p.m. to instruct the staff to find answers "before tomorrow." Staff emailed among themselves about how the Sacklers' demands were unrealistic and harmful, and then decided it was safer to discuss the problem by phone.

325. **In March**, Richard Sackler dug into Purdue's strategy for selling more OxyContin. He directed sales and marketing staff to turn over thousands of pieces of data about sales trends, including data to distinguish the kilograms of active drug from the number of prescriptions, so he could analyze higher doses. Staff delivered the data early Sunday morning; Richard responded with detailed instructions for new data that he wanted that same day. An employee sent Richard the additional data only a few hours later and pleaded with Richard: "I have done as much as I can." The employee explained that he needed to attend to family visiting from out of town. Richard responded by calling him at home, insisting that the sales

forecast was too low, and threatening that he would have the Board reject it. On Monday, staff emailed among themselves to prepare for meeting with Richard, highlighting that Richard was looking for results that could only be achieved by hiring more sales reps. Meanwhile, Richard met with John Stewart to discuss his analysis of the weekend's data and new graphs Richard had made.

326. Sales VP Russell Gasdia was struggling to handle the pressure. When Richard Sackler sent Gasdia a list of seven sales questions to answer on a Saturday (and copied Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler), Gasdia wrote to John Stewart:

> John, I know it is tricky, but Dr. Richard has to back off somewhat. He is pulling people in all directions, creating a lot of extra work and increasing pressure and stress. I will draft a response but he is not realistic in his expectations and it is very difficult to get him to understand.

327. Richard Sackler did not back off. Instead, he pushed staff to sell more of the highest doses of opioids and get more pills in each prescription. That same Saturday night, Richard sent Gasdia yet another set of instructions, directing him to identify tactics for "exceeding 2007 Rx numbers on an adjusted basis (adjusted for strength and average number of tablets per Rx)." The very next day, Gasdia was writing up plans for how adding sales reps, opioid savings cards, and promoting more intermediate doses of OxyContin could help increase sales.

328. Richard Sackler followed through on his weekend threat that he would have the Board reject the sales plan. Two days later, Richard circulated his own sales analysis to the Board, ordered the Secretary to "put this high in the Board agenda," and proposed that he and Mortimer Sackler oversee a redo of the annual plan as well as the 5-year plan for Purdue's opioids.

329. At the same time, Jonathan, Kathe, and Mortimer Sackler were also pushing staff about sales. Staff told those three Sacklers that they would use opioid savings cards to meet the

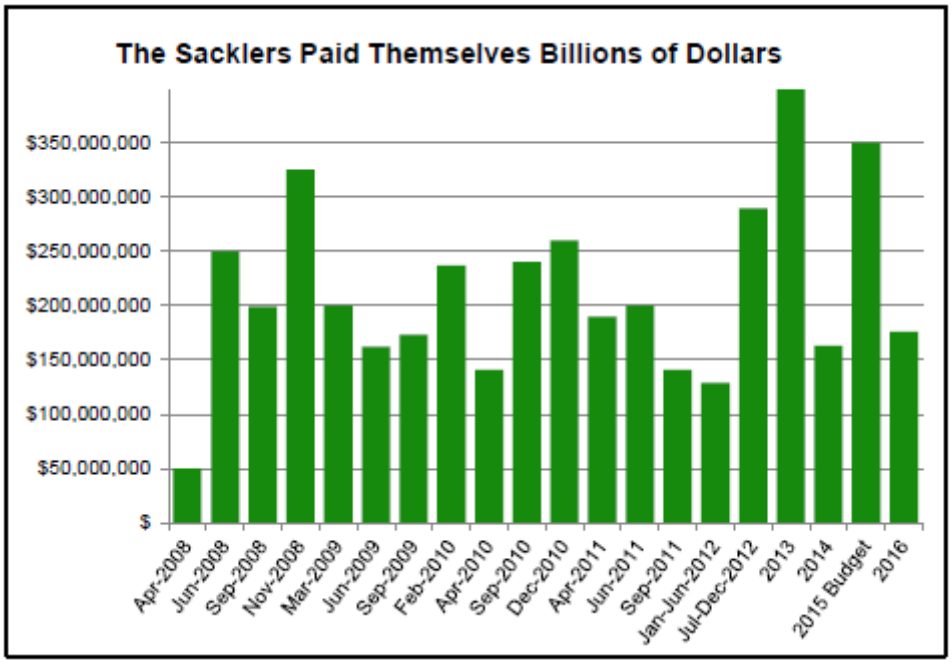
challenge of keeping OxyContin scripts at the same level in 2008 as in 2007, "in spite of all the pressures." Kathe demanded that staff identify the "pressures" and provide "quantification of their negative impact on projected sales."

330. **In April**, staff told the Sacklers that Purdue employed 304 sales reps. Staff reported to the Sacklers that the reps had obtained data showing which pharmacies stocked higher strengths of OxyContin, which helped them convince area doctors to prescribe the highest doses. Staff also told the Sacklers that Purdue received 853 Reports of Concern about abuse and diversion of Purdue opioids in Q1 2008, and they had conducted only 17 field inquiries in response. Staff also reported to the Sacklers that they received 83 tips to Purdue's compliance hotline during the quarter, but did not report any of them to the authorities.

331. On April 18, Richard Sackler sent Kathe, Ilene, David, Jonathan, and Mortimer Sackler a private memo about how to keep money flowing to their family. Richard wrote that Purdue's business posed a "dangerous concentration of risk." After the criminal investigations that almost reached the Sacklers, Richard wrote that it was crucial to install a CEO who would be loyal to the family: "People who will shift their loyalties rapidly under stress and temptation can become a liability from the owners' viewpoint." Richard recommended John Stewart for CEO because of his loyalty. Richard also proposed that the family should either sell Purdue in 2008 or, if they could not find a buyer, milk the profits out of the business and "distribute more free cash flow" to themselves.

332. That month, the Sacklers voted to have Purdue pay their family $50,000,000. From the 2007 convictions until 2018, the Sacklers voted dozens of times to pay out Purdue's

opioid profits to their family – in total ***more than four billion dollars***.



333. On April 18, the Sacklers voted to increase the 2008 budget for Sales and Promotion to $155,802,000. Then, Richard Sackler sent Sales VP Russell Gasdia a series of questions about Purdue's efforts to get patients to take higher doses and stay on opioids for longer times. Richard wanted to know how many Purdue patients had insurance that would let them take unlimited quantities of Purdue opioids; how many patients were limited to 60 tablets per month; and how many patients had any limit on the dose or number of tablets per day. He demanded that sales staff be assigned to answer his questions "by tomorrow morning." When the sales staff pleaded for a few more hours to collect the data, Richard agreed to give them until the end of the day.

334. **In May**, staff sent the Sacklers more ideas about ways to promote Purdue's opioids. The proposal matched the Sacklers' own plan, which Richard had written out as CEO: deflect blame from Purdue's addictive drugs by stigmatizing people who become addicted.

"KEY MESSAGES THAT WORK" included this dangerous lie: "It's not addiction, it's abuse. It's about personal responsibility."

335. **In June**, the Sacklers voted to appoint John Stewart as President and CEO of Purdue Pharma Inc. and Purdue Pharma LP. The appointment followed through on Richard Sackler's suggestion in his private memo that the Sacklers should put a premium on loyalty to the family. On the same day, the Sacklers voted to pay their family $250,000,000. The payment followed Richard Sackler's suggestion in the memo to "distribute more free cash flow" to themselves.

336. Meanwhile, Richard Sackler asked sales staff for more information about Purdue's opioid savings cards. Staff reported to Richard, Jonathan, Kathe, and Mortimer Sackler that 67,951 patients had used Purdue's opioid savings cards, and that the cards provided a discount on a patient's first five prescriptions.

337. After five prescriptions, many patients would face significant withdrawal symptoms if they tried to stop taking opioids. Staff told Richard, Jonathan, Kathe, and Mortimer Sackler that 27% of patients (more than 18,000 people) had used the cards for all five prescriptions.

338. **In July**, Purdue's Fleet Department reported to the Sacklers that Purdue had bought one hundred new Pontiac Vibes for the expanded sales force. Staff also told the Sacklers that Purdue received 890 Reports of Concern regarding abuse and diversion of Purdue's opioids in Q2 2008 and had conducted only 25 field inquiries in response. Staff reported to the Sacklers that they received 93 tips to Purdue's compliance hotline during the quarter, but did not report any of them to the authorities.

339. **In September**, the Sacklers voted to pay their family $199,012,182.

340. **In October**, staff told the Sacklers that surveillance data monitored by Purdue indicated a "wide geographic dispersion" of abuse and diversion of OxyContin "throughout the United States." Staff told the Sacklers that "availability of the product" and "prescribing practices" were key factors driving abuse and diversion of OxyContin. On the same day, staff told the Sacklers that Purdue had begun a new "Toppers Club sales contest" for sales reps to win bonuses, based on how much a rep increased OxyContin use in her territory and how much the rep increased the broader prescribing of opioids – the same "availability of product" and "prescribing practices" factors that worsen the risk of diversion and abuse. In the same report, staff told the Sacklers that they received 163 tips to Purdue's compliance hotline during Q3 2008, but did not report any of them to the authorities.

341. Staff also told the Sacklers that the Board-ordered sales force expansion had been implemented and Purdue now employed 414 sales reps.

342. **In November**, the Sacklers turned to expanding the sales force again. Purdue's 2009 budget identified expanding the sales force as the #1 sales and marketing objective. The Sacklers voted to spend $112,400,000 on sales reps. Staff told the Sacklers that their decision would pay an average sales rep salary of $89,708 and bonus of $43,470, and the sales reps would visit prescribers 518,359 times. Upon information and belief, many of those visits took place in Oklahoma, including in the 14 counties comprising the TJSA.

343. That same month, the Sacklers voted to pay their family $325,000,000. They also voted to pay $5,000,000 to Howard Udell – their lawyer and a convicted criminal. Like their February payment to Friedman, the Sacklers spent millions to keep the loyalty of people who knew the truth.

✣ ✣ ✣ ***2009*** ✣ ✣ ✣

344. **In March**, the Sacklers voted to pay Purdue sales reps and sales managers bonuses of 103 percent of Purdue's target because they sold so many opioids in 2008. The Sacklers also voted to increase the base pay of sales staff for 2009. On the same day, the Sacklers voted to pay their family $200,000,000.

345. **In April**, staff told the Sacklers that Purdue employed 412 sales reps and had made dramatic progress promoting higher doses: "[F]or the first time since January 2008, OxyContin 80mg strength tablets exceeded the 40mg strength." The Sacklers had a detailed conversation with Sales VP Russell Gasdia about the staffing of the sales force, how many sales reps the company should employ, and how many prescribers each rep would visit each year. The Sacklers told sales executives to hire a new staff member who would contact prescribers electronically and would promote Purdue opioids through the deceptive website *Partners Against Pain*.

346. Staff told the Sacklers that they received 122 tips to Purdue's compliance hotline during Q1 2009, and revealed one of them to an outside monitor. Staff reported to the Sacklers that the compliance problems included improper use of OxyContin marketing materials and opioid savings cards.

347. **In May**, staff told the Sacklers that Purdue had violated its Corporate Integrity Agreement with the U.S. government by failing to supervise its sales reps. Because sales reps lobbying doctors poses a high risk of misconduct (no witnesses, and the rep is paid to increase opioid sales), the U.S. government required that Purdue managers supervise sales reps in person at least 5 days each year. Purdue management disregarded that obligation and did not even set up a system to track it. Even though Purdue executives had ignored the requirement, they

responded to the violation by firing three employees in the field and letting all the executives at headquarters keep their jobs.

348. **In June**, Richard Sackler asked sales staff how a competing drug company had increased sales: "What is happening???" Staff replied that it was all about sales reps:

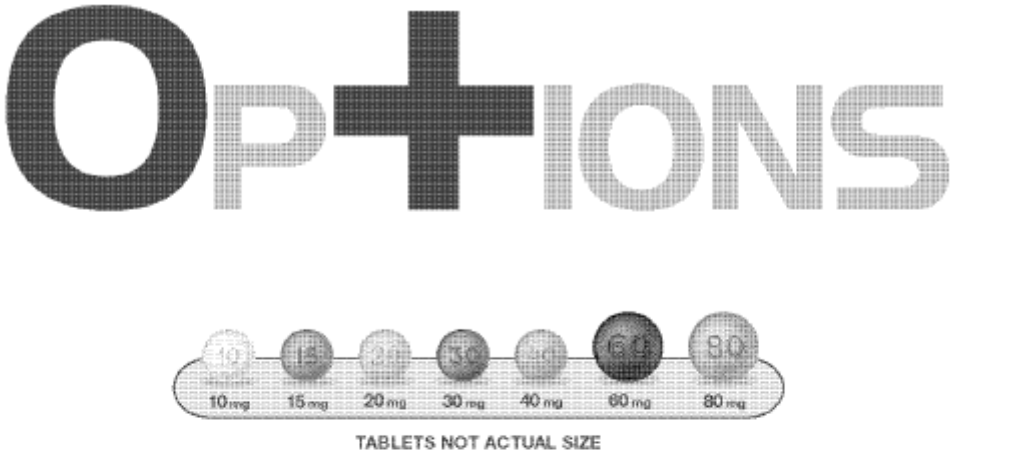
> They have 500 reps actively promoting to top decile MDs . . . Their messaging is "we are not OxyContin," alluding to not having the "baggage" that comes with OxyContin.
>
> Interestingly, their share is highest with MDs we have not called on due to our downsizing and up until last year, having half as many reps. Where we are competing head to head, we decrease their share by about 50%.

349. A few days later, staff reported to the Sacklers that Purdue had expanded its sales force at the Board's direction: "As approved in the 2009 Budget, 50 New Sales Territories have been created." Staff told the Sacklers the expansion was focused on the most prolific opioid prescribers, because "there are a significant number of the top prescribers" that Purdue had not been able to visit with its smaller force of sales reps. Later that month, the Sacklers voted to pay their family $162,000,000.

350. **In July**, staff told the Sacklers that Purdue employed 429 sales reps. Richard Sackler told staff that he was not satisfied with OxyContin sales and demanded a plan to "boost" them. He asked for the topic to be added to the agenda for the Board.

351. **In August**, Richard Sackler convened a meeting of Board members and staff about "all the efforts Sales and Marketing is doing and planning to do to reverse the decline in OxyContin tablets market." He emphasized that $200,000,000 in profit was at stake. At the meeting, staff told the Sacklers that the 80mg OxyContin pill was far-and-away Purdue's best performing drug. Purdue sold many more kilograms of active ingredient in the 80mg dose than any other dose (about 1,000 kilograms: literally over a ton of oxycodone).

352. Staff also reported to the Sacklers about their newest OxyContin sales campaign, with the slogan: *Options*. The *Options* campaign set the pattern that Purdue would follow for years: pushing doctors and patients up the ladder to higher doses. To make it easy for sales reps to promote higher doses, the campaign materials emphasized the "range of tablet strengths," provided a picture of each dose, and said: "You can adjust your patient's dose every 1 to 2 days." Staff told the Sacklers that they would advertise the *Options* campaign in medical journals reaching 245,000 doctors.



Purdue's 2009 marketing campaign 'Options'

353. Staff also reported to the Sacklers that more than 160,000 patients had used Purdue's opioid savings cards, more than doubling the result reported to the Sacklers the summer before. Staff also told the Sacklers that they would advertise OxyContin using a special television network: Thousands of doctors would be given free digital video recorders for their home televisions, in exchange for watching advertisements for drugs.

354. Immediately after meeting with sales staff, Richard Sackler asked for the raw data underlying their presentation. When staff had not responded within five minutes, he asked again.

355. **In September**, the Sacklers voted to pay their family $173,000,000. But Mortimer Sackler was concerned that staff were not selling Purdue's opioids aggressively enough. He demanded to know why staff predicted a decline in OxyContin sales when he believed the market should grow.

356. **In October**, staff told the Sacklers that Purdue had expanded its sales force by 50 territories and now employed 475 sales reps. Richard Sackler directed staff to send him weekly reports on OxyContin sales. No one in the company received reports that often, so staff were not sure how to reply. Staff considered telling Richard that there were no weekly reports, but they decided to make a new report just for him instead. The CEO also instructed the Sales Department to report to the Sacklers with more explanation about its activities.

357. That same month, the Sacklers and staff discussed federal sunshine legislation that would create a public database to disclose drug companies' payments to doctors. Purdue was paying many doctors to promote its opioids – including doctors in Oklahoma and the TJSA – but the payments could often be kept secret. Some of the Sacklers were concerned that doctors would be "much less willing" to work for Purdue if the payments were disclosed.

358. **In November**, the Sacklers voted to spend $121,628,000 to employ sales reps in 2010. Kathe and Richard Sackler were designated to review the sales projections. They also

voted to pay disgraced former employee Howard Udell up to another $1,000,000, and to pay $2,700,000 to settle personal injury claims by people harmed by Purdue's opioids.

359. At the Board meeting that month, Kathe and Richard Sackler asked staff to "identify specific programs that Sales and Marketing will implement to profitably grow the OER [extended-release oxycodone] market and OxyContin in light of competition; provide analytics around why/how the proposed increase in share-of-voice translates into sales and profitability growth; clarify the situation with respect to OxyContin being used by 35% of new patients, but only retaining 30% of ongoing patients;" and give the Sacklers a copy of a report from McKinsey on tactics to increase OxyContin sales. The McKinsey report instructed sales reps to maximize profits by "emphasizing [the] broad range of doses" – which was code for pushing the doses that were highest and most profitable.

360. At the same meeting, Richard Sackler also asked staff, "What are OxyContin's clinical advantages vs. Opana ER, MS Contin, Kadian, Exalgo, Avinza, Nucynta and Duragesic? How are these differences communicated?" In response, staff reported to all the Sacklers a list of claimed advantages of OxyContin over competing products, including that OxyContin purportedly reduces pain faster, has less variability in blood levels, and works for more pain conditions than competing drugs. These were all improper, unfair, and deceptive claims that Purdue had admitted were prohibited.

361. Richard Sackler also asked staff why Purdue's operating margin in 2010 was less than in 2009. Staff responded to all the Sacklers that one of the biggest reasons for the reduced margin was the cost of the expanded sales force that the Sacklers had ordered.

362. **In December**, Kathe and Richard Sackler met with sales staff to review plans for 2010. Staff warned the two Sacklers that, although OxyContin sales were at record-breaking

levels (nearly $3 billion per year), the decade-long rise in the total kilograms of oxycodone prescribed in America was beginning to flatten.

✣ ✣ ✣ ***2010*** ✣ ✣ ✣

363. **In January 2010**, Richard Sackler started the year by asking sales staff for new customized reports. Staff complained to each other until Sales VP Russell Gasdia asked CEO John Stewart to intervene: "Can you help with this? It seems like every week we get one off requests from Dr. Richard." Neither Stewart nor anyone else could keep Richard out of sales. Days later, Richard was writing to the sales employee on Saturday morning, ordering that his need to review the sales plan was "urgent" and should be satisfied "this weekend."

364. **In February**, Purdue's Sales and Marketing Department told the Sacklers that a key objective for 2010 would be to "[m]eet or exceed total prescriber call targets of 545,000" visits to prescribers to promote Purdue opioids. For the next four years or more, a key objective for the sales employees was to meet a quota of sales visits, and the Sacklers tracked their performance. The target rose from 545,000 prescriber visits in 2010, to 712,000 visits in 2011, 752,417 visits in 2012, and 744,777 visits in 2013. Upon information and belief, many of those visits took place in Oklahoma, including in the 14 counties comprising the TJSA.

365. To achieve the target for sales visits, staff told the Sacklers that another sales force expansion ordered by the Board had been implemented and Purdue employed 490 sales reps.

366. Staff also told the Sacklers that McKinsey estimated that new tactics by Purdue sales reps would generate $200,000,000 to $400,000,000 more in sales of OxyContin, and that sales reps had been practicing the new tactics in front of management. McKinsey had reported to Purdue on opportunities to increase prescriptions by convincing doctors that opioids provide "freedom" and "peace of mind" and give patients "the best possible chance to live a full and

active life." McKinsey also suggested sales "drivers" based on the ideas that opioids reduce stress and make patients more optimistic and less isolated. In fact, becoming addicted to opioids makes patients more stressed, more isolated, and less likely to survive.

367. The Sacklers voted to spend $226,000,000 on Sales and Promotion in 2010, and to pay their family $236,650,000.

368. **In March**, Richard Sackler instructed sales staff to send him monthly reports on sales of OxyContin and its competitors. They complied within ten minutes. The report showed that Purdue was selling more pills of its 80mg OxyContin (the highest dose) than any other dose, and that the highest dose pills were responsible for the greatest share of Purdue's revenue by far.

369. Staff also told the Sacklers that a key selling point for OxyContin compared to a competitor's product was that OxyContin could be used by patients who had not taken opioids before. Deceptively promoting opioids for opioid-naive patients who had not taken them before was one of the ways Purdue put patients at risk.

370. **In April**, the Sacklers voted to pay their family another $141,000,000.

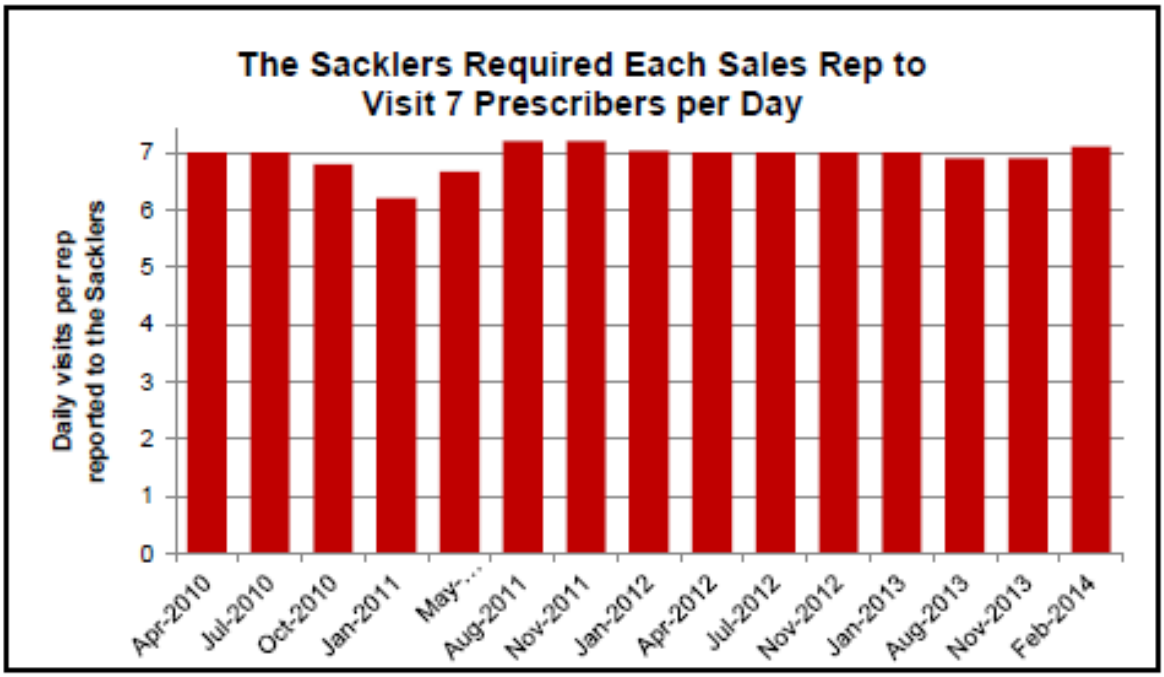
371. Meanwhile, staff told the Sacklers that they were pushing back against the "threat" of public health rules that would limit high doses of opioids. They told the Sacklers that Purdue would oppose precautions that asked doctors to consult with specialists before prescribing the highest doses.

✣ ✣ ✣ *The Sacklers' Control of Sales Visits* ✣ ✣ ✣

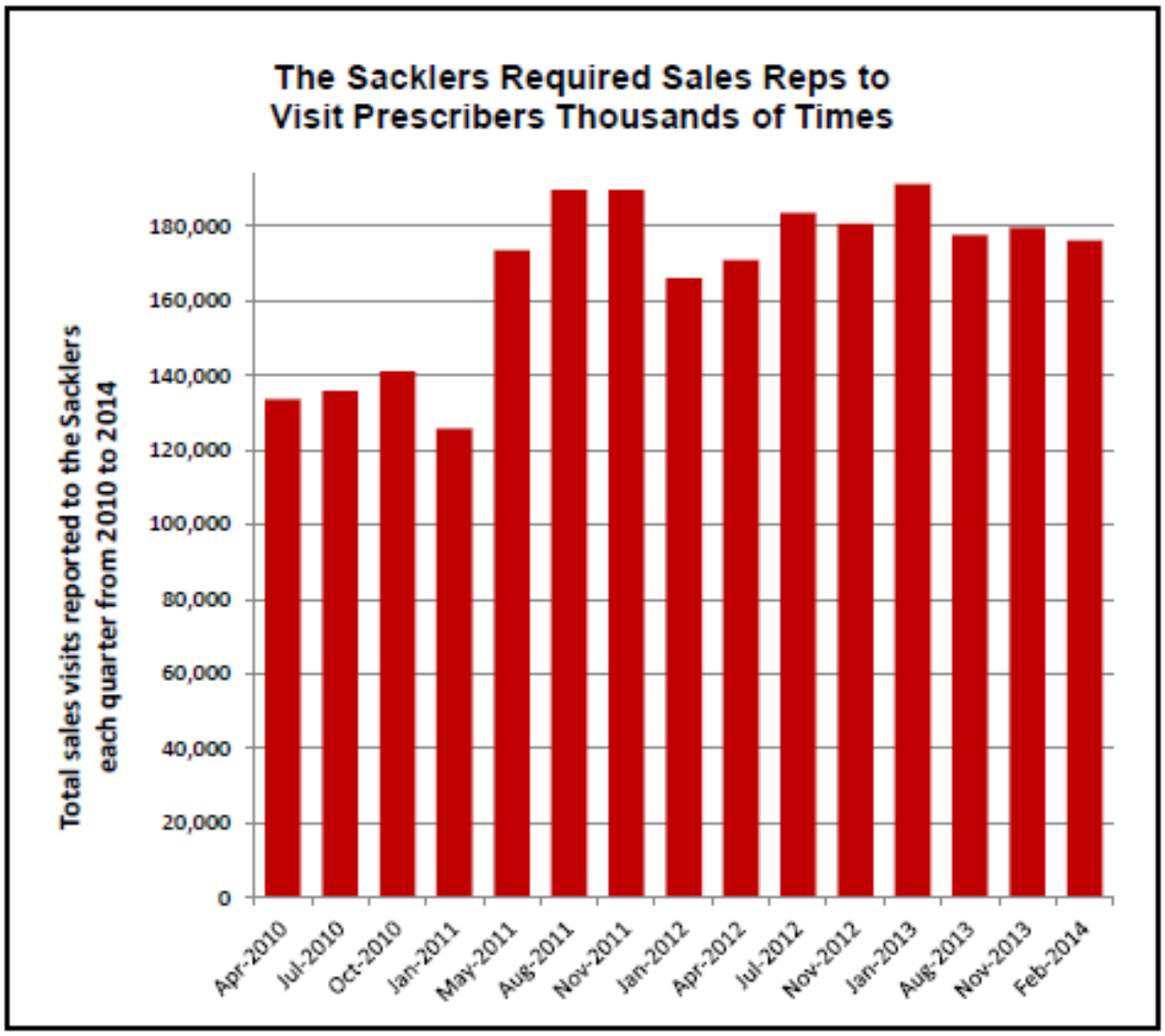
372. That same month (April 2010), staff gave the Sacklers one of many detailed reports on sales reps' visits to prescribers. As with every reference to "the Sacklers" before July 2012, that includes Beverly, Ilene, Jonathan, Kathe, Mortimer, Richard, and Theresa Sackler.

373. The Sacklers required each rep to visit an average of 7.5 prescribers per day. In April 2010, staff reported that they were falling short. During Q1 2010, reps had averaged only

7.0 visits per day. Staff promised to try harder. The Sacklers continued to set a target for daily sales visits for every sales rep, and they tracked the results, quarter by quarter, for at least the next four years. The results were always close to 7 visits per day.



374. The Sacklers also set targets for the total number of sales visits by the entire sales force per quarter – huge numbers that were always more than 100,000 visits. Meeting those targets was a top priority for the entire company. For Q1 2010, the target was to visit prescribers 127,376 times. Staff told the Sacklers that Purdue employed 489 sales reps and that, during Q1 2010, they achieved the goal. As with the daily visits per rep, the Sacklers tracked the total number of sales visits per quarter, every quarter, for at least the next four years.



375. The Sacklers also tracked the cost of the sales visits. In April 2010, staff reported to the Sacklers that each visit to a prescriber cost Purdue $219, and they were working to lower the cost to a target of $201. Upon information and belief, many of those visits took place in Oklahoma, including in the 14 counties comprising the TJSA.

376. **In June 2010**, staff gave the Sacklers an updated 10-year plan for growing Purdue's opioid sales. According to the plan, the Sacklers expected Purdue to pay their family at least $700,000,000 each year from 2010 through 2020. Beginning on page 1, staff emphasized that selling as many opioids as the Sacklers wanted "will require significant salesforce support,"

so the plan detailed the "optimization" of sales visits and the number of reps they would require. Sales VP Russell Gasdia wrote to the Sacklers that they planned for each rep to visit prescribers 1,540 times per year, so that 500 reps could make 770,000 visits at a cost of $212 per visit. He proposed to grow the sales force to 1,050 sales reps by 2015. To reach the Sacklers' expectations, Gasdia projected that Purdue would convince doctors to switch patients from Tylenol to Purdue's soon-to-be-released Butrans opioid, and Butrans would become a billion-dollar drug.

377. **In July**, Richard Sackler emailed staff just before the July 4th holiday weekend to demand more details about sales and marketing. Richard directed them to send to the Board plans for "the marketing program" and "the sales program," with instructions to "get this out before the weekend." A despondent staff member wrote to the CEO: "Are you expecting us to provide the marketing plan by tomorrow?" Staff came close to telling Richard Sackler no. Instead, they negotiated an extension and promised to provide full details about sales and marketing at the July Board meeting in Bermuda. To enforce the deal, Kathe Sackler ordered staff to circulate materials before the meeting.

378. By the Sacklers' choice, sitting on the Board of Purdue Pharma Inc. was a globe-trotting endeavor. The Sacklers held Board meetings for their U.S. drug company in a castle in Ireland, and in Bermuda, London, Portugal, Switzerland, New York, and Connecticut.

379. In Bermuda, the Sacklers focused on sales tactics again. Staff presented plans for selling Purdue's new Butrans opioid. Staff reported that sales reps would try to switch patients to opioids from NSAIDs like ibuprofen and explained tactics for convincing doctors that patients needed the new drug. Staff told the Sacklers that they had identified 82,092 prescribers to target with the Butrans sales campaign. Staff reported that they planned to add 125 sales reps and increase the number of prescriber visits by 30%.

380. Emails between staff and the Sacklers show that "the Board" (the Sacklers and at that point three other directors) responded with dozens of questions and orders about the sales campaign. The Board asked staff to determine whether sales would increase if they gave doctors free samples of opioids. The Board ordered staff to provide forecasts focused on higher doses of opioids. The Board demanded details about tactics Purdue sales staff used to influence doctors that Purdue viewed as "key opinion leaders," ("KOLs") who could influence other doctors to prescribe more opioids: "Provide the Board with more information on the strategy/tactics with respect to KOLs, how they are identified, how do we plan to interact with them, how do we see them helping build appropriate utilization of Butrans – and any other relevant information that will/could influence the prescribing of the product."

381. The Board pushed staff about whether they were describing the benefits of opioids aggressively enough. Purdue was not legally allowed to say that Butrans was effective for 7 days, because the evidence did not show that, but the Board wanted to know why Purdue didn't claim 7 days of effectiveness in its marketing.

382. Purdue was not legally allowed to say that Butrans was effective for osteoarthritis ("OA") because the clinical trials testing Butrans for patients with OA had failed, but the Board wanted to know if sales reps could sell more by remaining silent about the failed trial: "What can be said in response to a prescriber who asks directly or indirectly, 'can this product be prescribed for my patient with OA?' In responding are we required to specifically mention the failed trials in OA?"

383. At that same Board meeting in Bermuda, the Sacklers voted to expand the sales force by 125 more sales reps. They ordered that the hiring begin in September 2010 and be completed before the National Sales Meeting in January 2011. They also directed Purdue to hire

18 more managers to supervise the reps.

384. Later that month, staff told the Sacklers that Purdue employed 491 sales reps and that, during Q2 2010, they visited prescribers 135,824 times. Upon information and belief, many of those visits took place in Oklahoma, including in the 14 counties comprising the TJSA. Meanwhile, staff told the Sacklers that Purdue had paid their family $389,000,000 in the first six months of 2010.

385. **In August**, the Sacklers continued to focus on the sales force. That month, they decided not to acquire a new insomnia drug because of the risk that promoting it could distract sales reps from selling Purdue's opioids. Richard Sackler concluded that "loss of focus" in sales reps' meetings with prescribers was too great a risk, and the Sacklers decided not to go through with the deal.

386. A few days later, the Sacklers discussed abuse of OxyContin. Staff told them that the most common way of abusing oxycodone, by far, was swallowing it – which a crush-proof coating on OxyContin did not affect. The prescription monitoring program identifies "doctor-shopping" when a patient gets opioids from multiple prescribers – an indication that the patient is at risk of addiction, overdose, and death.

387. **In September**, staff reported to the Sacklers about the Board's July 2010 decision to hire more sales reps. Staff said they were working to implement the decision, adding 125 sales territories. Staff also told the Sacklers that 82% of prescriptions for OxyContin were to patients who were already on the drug – a key ingredient in Purdue's plans to keep patients on opioids longer. The Sacklers voted to pay their family $240,000,000.

388. **In October**, staff told the Sacklers that Purdue employed 506 sales reps and, during Q3 2010, they visited prescribers 141,116 times. Upon information and belief, many of those visits took place in Oklahoma, including in the 14 counties comprising the TJSA.

389. Meanwhile, staff told the Sacklers that Purdue had paid their family $629,000,000 in the first nine months of 2010. The Sacklers voted to pay another $12,000,000 to settle claims of more patients injured by OxyContin.

390. **In November**, staff warned the Sacklers that doctors were not prescribing Purdue's highest dose and most profitable opioids as much as the company had expected, so it might be necessary to cut the family's quarter-end payout from $320,000,000 to $260,000,000 and distribute it in two parts: one in early December and one closer to the end of the month. Mortimer Sackler objected to the decrease and the division into two payments, and he demanded answers from staff: "Why are you BOTH reducing the amount of the distribution and delaying it and splitting it in two?" "Just a few weeks ago you agreed to distribute the full 320 [million dollars] in November."

391. Staff also told the Sacklers that the expansion of the sales force that the Sacklers had ordered was being implemented, including 125 new sales territories. The Sacklers voted to spend $158,086,000 to employ sales reps in 2011.

392. Staff also reported to the Sacklers that drug company leaders can be punished for breaking the law and "owners, officers, and managers will especially face even more serious scrutiny in the future."

393. **In December**, the Sacklers voted to pay their family $260,000,000.

✣ ✣ ✣ ***2011*** ✣ ✣ ✣

394. **In January 2011**, Richard Sackler met with sales reps for several days at the Butrans Launch Meeting and discussed how they would promote Purdue's newest opioid. Richard quickly followed up with sales management to demand a briefing on how the sales visits were going in the field:

> I'd like a briefing on the field experience and intelligence regarding Butrans. How are we doing, are we encountering the resistance that we expected and how well are we overcoming it, and are the responses similar to, better, or worse than when we marketed OxyContin® tablets?

395. Richard's interventions into sales tactics made employees nervous. When Richard followed up to ask for information "tomorrow," CEO John Stewart tried to slow things down, warning staff that Richard's requests would be "never-ending." Stewart was right about Richard, but wrong to think he could stand in the way.

396. Two hours after sending his request, Richard ordered Sales VP Russell Gasdia to call him, on a Sunday morning, on his cell phone. Richard wanted to discuss "the resistance" and how Purdue's sales reps were "overcoming" it right away.

397. Richard Sackler kept pushing for more sales. After one week of prescriptions doubled Purdue's forecast, Richard wrote to the sales staff: "I had hoped for better results." In a follow-up message, Richard asked staff to tell him the ratio of prescriptions per sales representative visit to a prescriber, divided out by the prescribers' specialties. He asked for a Board discussion of the barriers that sales reps were encountering during promotion. After trying to answer Richard's questions and getting another dissatisfied response, sales staff wrote to the CEO to ask him to intervene. In a later message, Richard wrote to the staff again: "What do I have to do to get a weekly report on Butrans sales without having to ask for it?" One exasperated staff member begged another to respond. The CEO announced that, from then on, staff would send a sales report to the Sacklers every week. When staff sent the first weekly report, Richard responded immediately: "What else more can we do to energize the sales and grow at a faster rate?" The next week, Richard wrote to the sales staff to ask about the performance of a specific sales rep.

398. Mortimer Sackler jumped in, asking staff for more information about sales. When two days passed without an answer, Mortimer insisted: "Any answer to this yet?" Staff rushed to prepare answers to share with all the Sacklers.

399. The people who worked for the Sacklers knew their appetite for sales was extreme. When the launch of Purdue's Butrans opioid was on track to beat every drug in its class, Richard Sackler asked sales staff: "Do you share my disappointment?" Sales VP Russell Gasdia replied privately to the CEO: "As far as his disappointment, I do not share that."

400. Throughout that spring of 2011, the Sacklers kept up a drumbeat of aggressive sales tactics, multi-million-dollar payouts, and disregard for the law. In January, the Sacklers voted to pay the legal expenses of specific individuals if they were defendants or witnesses in investigations of Purdue, including several sales executives and John Crowley, Executive Director of Controlled Substances Act Compliance. The Sacklers knew these employees were aware of misconduct because they had directed it. In September 2009, a Purdue sales manager had emailed Crowley that Purdue was promoting opioids to an illegal pill mill: "I feel very certain this is an organized drug ring," and "Shouldn't the DEA be contacted about this?" Purdue sat on the information and did not report it to the authorities *for more than two years,* until after the pill mill doctor had already been arrested and the Sacklers had arranged for lawyers in case Crowley was questioned.

401. **In January**, staff reported to the Sacklers that a key initiative in Q4 2010 had been the expansion of the sales force. Staff told the Sacklers that Purdue employed 590 sales reps and, during Q4 2010, they visited prescribers 125,712 times. Upon information and belief, many of those visits took place in Oklahoma, including in the 14 counties comprising the TJSA.

402. Staff told the Sacklers that Purdue paid their family $889,000,000 in 2010. But staff reported that Purdue's revenue was still hundreds of millions of dollars less than expected

because doctors were prescribing fewer of Purdue's highest dose opioids. Staff told the Sacklers that sales of the highest doses continued to fall below expectations, and the gap had cost the company $120,000,000 in the month of December 2010 alone. The Sacklers faced the prospect that, if doctors did not prescribe more of the highest doses, their payouts would shrink.

403. **In February**, staff reported to the Sacklers that law enforcement was increasingly concerned about lawbreaking by drug companies and the resulting "danger to public safety." Staff also told the Sacklers that Purdue was receiving a rising volume of hotline calls and other compliance matters, reaching an all-time high during Q4 2010. Staff reported to the Sacklers that sales reps had engaged in improper promotion of Purdue opioids, but the company had decided not to report the violations to the government. Staff also reported to the Sacklers about the risks of OxyContin, including that 83% of patients in substance abuse treatment centers began abusing opioids by swallowing pills, and that it took, on average, 20 months for a patient to get treatment. Staff reported to the Sacklers that Purdue tracked to individual zip codes the correlation between poison control calls for OxyContin overdose, pharmacy thefts, and prescribers Purdue suspected of abuse and diversion in *Region Zero*.

404. **In April**, the Sacklers met with Sales VP Russell Gasdia to talk about sales. He told them that OxyContin was the best-selling painkiller in America, with more than $3 billion in annual sales – almost double the second-place drug. The Sacklers voted to pay their family $189,700,000.

405. **In May**, in response to the Sacklers' repeated requests, staff sent Richard, Jonathan, Kathe, Mortimer, and Theresa Sackler a report on the sales tactics reps were using to push Butrans. The first tactic reported to these Sacklers was to focus on a select "core" of physicians that Purdue calculated would be most susceptible to sales reps lobbying to prescribe more opioids.

406. The second tactic staff reported to Richard, Jonathan, Kathe, Mortimer, and Theresa Sackler in the May 25, 2011 email was "positioning of Butrans for specific patient types."

407. A third tactic reported to these five Sacklers was getting prescribers to commit to put specific patients on opioids.

408. Jonathan Sackler was not satisfied that these tactics would be enough to boost sales. He wrote to John Stewart: "[T]his is starting to look ugly. Let's talk." Stewart and the sales team scrambled to put together a response and set up a meeting with Jonathan for the following week.

409. That same month, staff reported to the Sacklers that Purdue had hired 47 more sales reps according to the Sacklers' orders. Staff told the Sacklers that Purdue employed 639 sales reps and, during Q1 2011, they visited prescribers 173,647 times. Upon information and belief, many of those visits took place in Oklahoma, including in the 14 counties comprising the TJSA.

410. Meanwhile, the Sacklers voted to pay $10,000,000 to try to settle a lawsuit by the Attorney General of Kentucky regarding Purdue's marketing of OxyContin. The Sacklers were on notice that Purdue's unfair and deceptive marketing raised serious concerns. Staff also told the Sacklers that they had received another 88 calls to Purdue's compliance hotline, but not reported any of them to the authorities.

411. **In June**, staff reported to the Sacklers that Purdue's opioid sales were hundreds of millions of dollars less than expected and that a prime reason was that doctors were not prescribing enough of the highest doses. The headline presented at the Board meeting read: "40 and 80mg tablet prescriptions have decreased significantly. The 10mg and 20mg tablet prescriptions initially increased, but given their lower value not enough to offset the higher

strength decline." Staff told the Sacklers: "As a result of the change in prescriptions by strength, OxyContin brand Kgs dispensed are below mid 2010 levels." Staff reported to the Sacklers that Purdue would rely on sales rep visits and paid physician spokespersons to maintain demand. For a "Super Core" of "Very High Potential" opioid prescribers, Purdue would order its sales reps to make sales visits *every week*.

412. The Sacklers immediately pushed to find ways to increase sales. Richard Sackler asked Sales VP Russell Gasdia to include him in a meeting with District Managers who were the day-to-day supervisors of the sales reps. Then, having missed the meeting, he engaged Gasdia again by email. Gasdia told Richard that Purdue had hired 147 new sales reps at the Board's direction. Gasdia told Richard that Purdue instructed the sales reps to focus on converting patients who had never been on opioids or patients taking "low dose Vicodin, Percocet, or tramadol" – all patients for whom Purdue's opioids posed an increase in risk.

413. Gasdia told Richard Sackler (again) that Purdue instructed sales reps to focus on the few highest-prescribing doctors in their territory and visit them over and over. Gasdia also told Richard that staff had initiated performance enhancement plans for sales reps who were not generating enough opioid prescriptions.

414. In response to Gasdia's message about the sales reps, Richard Sackler wrote back six minutes later and asked to meet with Gasdia without delay. Gasdia scrambled to schedule a meeting about sales tactics with Richard for first thing the next morning. Richard would not wait until the morning and instructed Gasdia to call him that same day.

415. Richard Sackler continued the correspondence that day, criticizing Purdue's managers for allowing sales reps to target "non-high potential prescribers." "How can our managers have allowed this to happen?" Richard insisted that sales reps push the doctors who prescribed the most drugs.

416. To make sure his orders were followed, Richard Sackler demanded to be sent into the field with the sales reps. Richard wanted a week shadowing Purdue sales reps, two reps per day. In horror, Gasdia appealed to Purdue's Chief Compliance Officer, warning that Richard Sackler promoting opioids was "a potential compliance risk." Compliance replied: "LOL." To make sure the Sacklers' involvement in marketing stayed secret, staff instructed: "Richard needs to be mum and be anonymous."

To: Gasdia, Russell[Russell.Gasdia@pharma.com]
From: Weinstein, Bert
Sent: Thur 6/16/2011 7:47:14 PM
Subject: Re: Feedback from District Manager Advisory Council - FYI

LOL - I told him you raised concerns with me. We agreed Richard needs to be mum and be anonymous

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From: Gasdia, Russell
To: Weinstein, Bert
Sent: Thu Jun 16 17:08:15 2011
Subject: Fw: Feedback from District Manager Advisory Council - FYI

I spoke to John and he said Stuart cleared Dr Richard observing calls with reps. I told him I spoke with you and you have concerns...he said he'd speak with you.

From: Sackler, Dr Richard
To: Gasdia, Russell
Cc: JHS (US)
Sent: Thu Jun 16 16:45:56 2011
Subject: Re: Feedback from District Manager Advisory Council - FYI

Russ,
One more thing. Who have you chosen for me to go to the field with the week after the budget meetings? Where are they? Can we conveniently do two reps each day especially if I travel to get to the right place as I probably should do.

Purdue internal emails

417. A slew of executives, including the CEO, got involved in planning Richard Sackler's sales visits. All of them were worried. One wrote:

> About 5 last night, John [Stewart, the CEO] was walking by my office – I yelled out to stop him – and said that you had mentioned to me that Richard wanted to go into the field, and that you had raised concerns with me. John seemed angry, and asked if I had concerns. I told him could be issues and Richard could be out on a limb if he spoke about product at all or got into conversations with HCPs, or identified himself, especially with FDA Bad Ad possibilities. John agreed Richard would have to be mum throughout, and not identify himself other than as a home office person.

418. Richard Sackler indeed went into the field to promote opioids to doctors alongside a sales rep. When he returned, Richard argued to the Vice President of Sales that a legally-required warning about Purdue's opioids wasn't needed. He asserted that the warning "implies a danger of untoward reactions and hazards that simply aren't there." Richard insisted there should be "less threatening" ways to describe Purdue opioids.

419. Meanwhile, the Sacklers voted to pay their family $200,000,000.

420. A few days later, sales and marketing staff scrambled to prepare responses to questions from the Sacklers. Mortimer Sackler asked about launching a generic version of OxyContin to "capture more cost sensitive patients." Kathe Sackler recommended looking at the characteristics of patients who had switched to OxyContin to see if Purdue could identify more patients to convert. Jonathan Sackler wanted to study changes in market share for opioids, focusing on dose strength.

421. At the same time, sales staff were organizing more ways for Richard Sackler to oversee their work in the field. Gasdia proposed to Richard:

> In addition to field contacts with representatives, you may want to consider attending one of the upcoming conventions where we will be attending. At each of the ones listed below, we will have a promotional booth for OxyContin & Butrans. In addition, we are sponsoring educational programs for Butrans and OxyContin in the form of a "Product Theater."
>
> This would provide you the opportunity to be on the convention floor, observing numerous presentations being provided by our representatives and see a wide range of interactions over the course of a day. In addition,

> we can arrange for one-on-one meetings with key opinion leaders who are attending, many of them are approved consultants/advisors for us and you can have some open conversations regarding the market, perceptions around Butrans and OxyContin. Finally, you could observe the Product Theaters we are implementing.

422. **In July**, staff assured the Sacklers that Purdue prohibited sales reps from writing their sales pitches to prescribers in email.

423. **In August**, staff told the Sacklers that Purdue employed 640 sales reps and, during Q2 2011, they visited prescribers 189,650 times. Upon information and belief, many of those visits took place in Oklahoma, including in the 14 counties comprising the TJSA.

424. Meanwhile, staff reported to the Sacklers that, in the first seven months of 2011, Purdue paid the family $411,000,000.

425. **In September**, Richard Sackler directed staff to study a savings card program for a widely-used cholesterol medication (not an addictive narcotic) to learn how Purdue could use it for opioids. That same month, the Sacklers voted to pay their family $140,800,000 more.

426. **In November**, staff told the Sacklers that Purdue still employed 640 sales reps and, during Q3 2011, they visited prescribers 189,698 times. Upon information and belief, many of those visits took place in Oklahoma, including in the 14 counties comprising the TJSA. Looking ahead, the Sacklers voted to spend $162,682,000 to employ sales reps in 2012.

427. Meanwhile, staff told the Sacklers that, in the first nine months of 2011, Purdue paid their family $551,000,000.

✣ ✣ ✣ ***2012*** ✣ ✣ ✣

428. **In January 2012**, Jonathan Sackler started the year pressing Sales VP Russell Gasdia for weekly updates on sales. A few days later, Richard Sackler jumped into the weeds with the sales staff, this time about advertising. Richard noticed that online ads appeared indiscriminately on webpages with content associated with the ad – regardless of whether the association was positive or negative. Staff assured Richard that, when Purdue bought online advertising for opioids, it specified that the ads appear only on pages expressing positive views toward opioids, and would not appear with articles "about how useless or damaging or dangerous is our product that we are trying to promote."

429. That same month, staff told the Sacklers that Purdue employed 632 sales reps and, during Q4 2011, they visited prescribers 165,994 times. Upon information and belief, many of those visits took place in Oklahoma, including in the 14 counties comprising the TJSA.

430. The Sacklers were not satisfied with the sales effort. In February, staff reported to the Sacklers that prescriptions had dropped, and that a decrease in sales rep visits to prescribers was a major driver of the decline. Staff asked the Sacklers to be patient, because reps had missed work for December holidays and the company's mandatory National Sales Meeting in January. Mortimer Sackler was not pleased. He suggested that, "in future years we should not plan the national sales meeting so close following the winter break as it extends the period of time since the doctor last saw our rep." Mortimer wrote: "Wouldn't it be better to have the reps get back to work for January and back in front of doctors." Mortimer was agitated by the thought of doctors going too many days without a sales rep visiting to promote Purdue opioids. If Purdue rescheduled its meeting, "[a]t least then the doctors will have gotten at least one reminder visit from our reps in the last month whereas now they might go two months without seeing one of our reps??" Staff replied to Mortimer, arguing for "balance." Richard Sackler replied within

minutes that, since the National Sales Meeting prevented sales reps from visiting doctors, "Maybe the thing to have done was not have the meeting at all." Purdue's compliance officer forwarded the exchange to his staff, commenting: "Oh dear."

431. Meanwhile, Richard Sackler interrupted sales staff many times a day, often in a hurry: "I had hoped you would have updated this," "Will I have it by noon?" "get to this ASAP." Staff advised each other: "avoid as much e mail with dr. r as you can." Sales VP Russell Gasdia wrote to the CEO in exasperation: "I'm not sure what we can do about Dr. Richard."

432. Throughout the spring, the Sacklers pressed staff to promote Purdue's opioids more aggressively. In February, Gasdia wrote to sales staff that the Board was not satisfied with the money coming in: "Things are not good at the [Board] level." When sales dropped for one week on account of the Presidents' Day holiday, Richard Sackler wrote to sales management: "This is bad." Gasdia forwarded Richard's message to his colleagues, asking how they could "create a greater sense of urgency at the regional management and district management level."

433. Meanwhile, Gasdia pleaded with the CEO to defend him against Richard Sackler's micromanagement of sales: "Anything you can do to reduce the direct contact of Richard into the organization is appreciated." A week later, Richard wrote to sales management again to criticize them for U.S. sales being "among the worst" in the world.

434. **In March**, staff sent the Sacklers a revised 2012 budget that cut the proposed payout to their family from $472,500,000 to $418,200,000.

435. On one Saturday morning, Richard Sackler wrote to marketing staff, demanding monthly data for all extended release pain medications for the past twelve years and an immediate meeting that Monday night. Gasdia and Stewart stood by helpless, writing: "Do let us know how this goes." Later that month, staff created for Richard a historical summary of key

events determining OxyContin sales. Eleven of the key events in sales history were changes in the size of the Purdue sales force – all known to Richard because the Sacklers had ordered them.

436. A few days later, staff sent Richard Sackler an assessment of recently-improved opioid sales. Staff told Richard that the increase in prescriptions was caused by tactics that Purdue taught sales reps: pushing opioids for elderly patients with arthritis ("proper patient selection") and encouraging doctors to use higher doses of opioids ("quick titration"). In the coming months, Purdue would study, document, and expand the use of higher doses to increase sales.

437. Richard Sackler wrote that he was not satisfied with a report on sales and instructed Gasdia to discuss it with him within a day. Gasdia scrambled to schedule the meeting. Then Richard raised the stakes and asked Gasdia to address both Butrans sales tactics and a decline in OxyContin sales and propose corrective actions. John Stewart suggested that Richard's frustrations could be linked to dosing: He encouraged Gasdia to tell Richard that patients on lower doses seemed to stop taking opioids sooner, and that much of the profit that Purdue had lost had been from doctors backing off the highest dose of OxyContin (80mg).

438. Richard Sackler was not satisfied. Days later, after sales did not increase, staff told him that they were starting quantitative research to determine why patients stay on opioids, so they could find ways to sell more opioids at higher doses for longer.

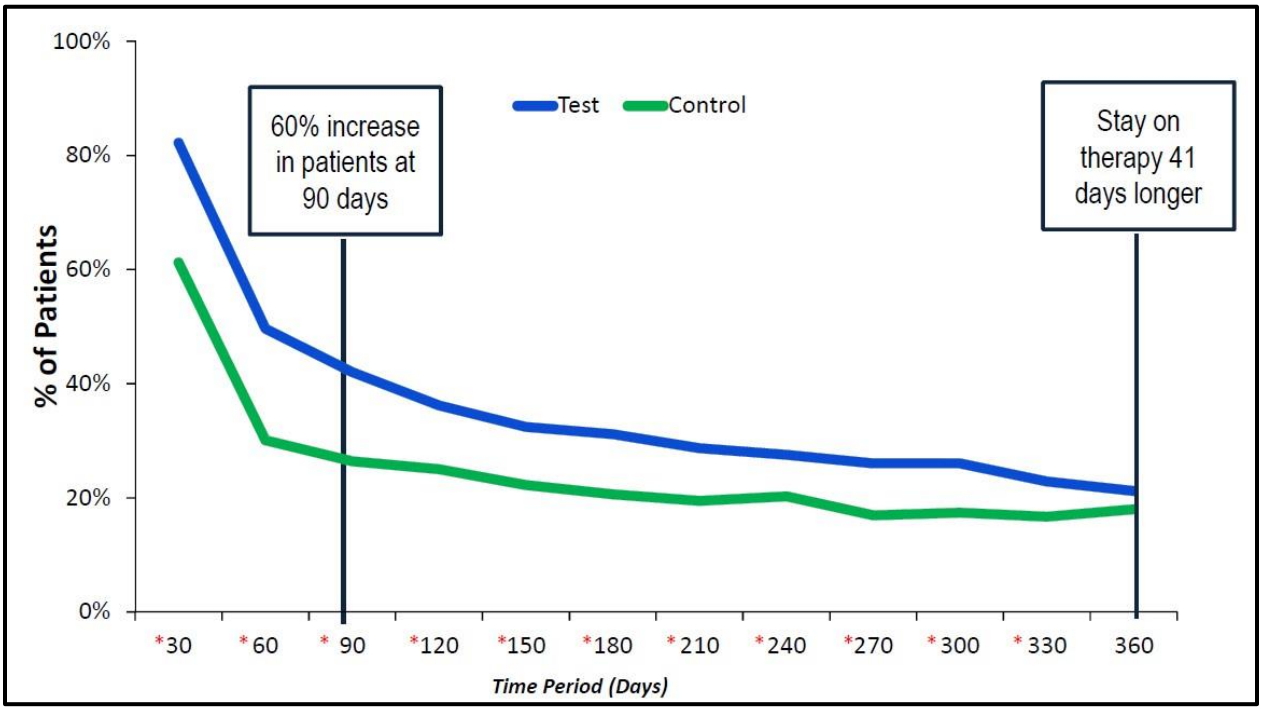
439. **In April**, staff told the Sacklers that Purdue employed 630 sales reps and, during Q1 2012, they visited prescribers 179,554 times. Upon information and belief, many of those visits took place in Oklahoma, including in the 14 counties comprising the TJSA.

440. Meanwhile, Richard Sackler kept pushing the staff to increase sales. When the mandatory weekly report to the Sacklers showed that sales reps achieved 9,021 prescriptions in a week, Richard asked Sales VP Russell Gasdia for a commitment that the reps would get weekly

prescriptions to 10,000: "Are you committed to breaking 10K/wk Rx's this month?" A colleague replied incredulously to Gasdia: "Is there any question of your commitment?" Even for people who worked in sales, Richard's conviction that sales reps should just make doctors prescribe opioids seemed crazy.

441. Gasdia tried to assure Richard Sackler that they were selling opioids aggressively: "Windell and the sales force, as well as Mike and the marketing team (initiatives being implemented) are focused and committed to accelerating the growth trend . . . everyone in the commercial organization is focused on exceeding the annual forecast." Richard wanted more. Richard wanted to know what tactics sales staff would use to get more prescriptions, and he wanted to talk about it right away. First he wrote: "[G]ive me the table of weekly Rx plan and the actual. Then show how you plan to make up the current shortfall." Then he asked for a meeting within 24 hours. Then Richard did not want to wait that long: "Can we meet in person today?" Sales and marketing staff soon met with Richard to review how they would sell more opioids.

442. **In June**, the Sacklers discussed sales and marketing again. Staff reported to the Sacklers that they had added 120,000 sales visits to drive sales of OxyContin. Staff also told the Sacklers that they expanded the opioid savings cards, because Purdue's latest data showed opioid savings cards led to 60% more patients remaining on OxyContin longer than 90 days. The Sacklers reviewed the results of Purdue's confidential studies showing that opioid savings cards kept more patients on opioids for 90 days, 120 days, 150 days, 180 days, 210 days, 240 days – even an entire year.



Purdue internal analysis about keeping patients on opioids longer

Keeping patients on opioids for these lengths of time was especially dangerous for the patients and especially profitable for Purdue.

443. Staff also told the Sacklers that (as they had in 2009) they were again targeting prescribers for OxyContin promotion through a special television network.

444. **In July**, David Sackler (Richard Sackler's son) took a seat on the Board. For events after July 2012, this Complaint includes David in "the Sacklers."

445. At one point, staff calculated that Purdue was spending more than $9,000,000 per year to buy food for doctors who prescribe opioids.

446. Staff also told the Sacklers that Purdue employed 633 sales reps and, during Q2 2012, they visited prescribers 183,636 times. Upon information and belief, many of those visits took place in Oklahoma, including in the 14 counties comprising the TJSA.

447. **In August**, the Sacklers voted to direct Purdue to recruit an additional marketing executive and make candidates available to meet with members of the Board.

448. **In November**, staff told the Sacklers the results of an internal study of 57,000 patients that Purdue performed explicitly to determine how opioid dose "influences patient length of therapy." The results showed that patients on the highest doses "are the most persistent." The "Recommended Actions" presented to the Sacklers included "additional workshops for the sales force" and "specific direction" to the sales reps about using higher doses to keep patients on drugs longer. Staff told the Sacklers that encouraging higher doses "is a focal point of our promotion," and that sales reps would "emphasize the importance" of increasing patients' opioid doses, as soon as three days after starting treatment.

449. That same month, the Sacklers voted to set Purdue's budget for Sales and Promotion for 2013 at $312,563,000. Staff told the Sacklers that Purdue employed 622 sales reps and, during Q3 2012, they visited prescribers 180,723 times.

✣ ✣ ✣ ***2013*** ✣ ✣ ✣

450. **In January 2013**, in what was becoming a yearly ritual, Richard Sackler questioned staff about the drop in opioid prescriptions caused by Purdue sales reps taking time off for the holidays. Richard wasn't satisfied: "Really don't understand why this happens. What about refills last week? Was our share up or down?" Staff assured Richard that doctors were "sensitive" to sales rep visits and, as soon as the reps got back into action, they would "boost" opioid prescriptions again.

451. Staff told the Sacklers that they continued to reinforce the *Individualize the Dose* campaign, which the Sacklers knew would and intended to use to promote higher doses. Staff also told the Sacklers that sales reps would place greater emphasis on the opioid savings cards,

which the Sacklers knew would and intended to use tokeep patients on opioids longer. Staff reported to the Sacklers that Purdue had conducted a sensitivity analysis on the opioid savings cards to maximize their impact and, as a result, had increased the dollar value and set the program period to be *15 months* long. Staff also reported to the Sacklers that Purdue had created promotional materials to support these tactics and had distributed them to the sales force. Staff also told the Sacklers that Purdue showed an opioid promotional video to 5,250 physicians on the Physician's Television Network. The video urged doctors to give patients Purdue's opioid savings cards.

452. That same month, staff told the Sacklers that Purdue employed 609 sales reps and, during Q4 2012, they visited prescribers 153,890 times. Upon information and belief, many of those visits took place in Oklahoma, including in the 14 counties comprising the TJSA.

453. **In February**, the Sacklers met with staff about tactics for promoting Purdue's opioids. They discussed research on what influences prescriptions, how doctors had responded to Purdue's increased promotion, and sales force promotion themes. On the same day, the Sacklers voted to award bonuses and salary increases to executives, including those involved in marketing Purdue's opioids.

454. **In March**, staff reported to the Sacklers on the devastation caused by prescription opioids. Staff told the Sacklers that drug overdose deaths had more than tripled since 1990 – the period during which Purdue had made OxyContin the best-selling painkiller. Staff told the Sacklers that tens of thousands of deaths were only the "tip of the iceberg." Staff reported that, for every death, there were more than a hundred people suffering from prescription opioid dependence or abuse.

455. **In May**, staff reported to the Sacklers again that they were successfully using opioid savings cards to get patients to "remain on therapy longer." Staff told the Sacklers that they were using direct mail and email, as well as sales visits, to push the opioid savings cards.

456. Staff reported to the Sacklers that, despite these sales efforts, they were not achieving the goals of getting enough patients on higher doses of opioids and getting doctors to prescribe more pills in each prescription. Staff told them that "there is an 'unfavorable' mix of prescriptions across strengths," and Purdue was losing tens of millions of dollars in revenue because sales of the highest doses (60mg and 80mg) were too low. Staff told the Sacklers that there was also a second problem: "lower average tablet counts per prescription." Because doctors were not prescribing enough pills during each patient visit, Purdue was losing tens of millions of dollars in revenue. Staff promised the Sacklers: "A deeper analysis is underway to determine the cause of the decline in the 30mg, 60mg, and 80mg tablet strengths, as well as the lower than budgeted average tablets per prescription. Once the analysis is complete, we will have a better sense of what tactics to implement to address both issues."

457. The Sacklers met with Sales VP Russell Gasdia about the strategy for selling high doses. Gasdia told the Sacklers that, "[t]itration up to higher strengths, especially the 40mg and 80mg strengths is declining." He analyzed the "Causes of OxyContin's Decline in Higher Strengths," and how Purdue would reverse that decline. He told the Sacklers that Purdue's #1 tactic to sell higher doses was sending sales reps to visit prescribers. The #2 tactic was a marketing campaign designed to promote high doses – Purdue's *Individualize the Dose* campaign. After that, Gasdia told the Sacklers, came opioid savings cards. After that, special focus on the most prolific opioid prescribers.

458. Gasdia told the Sacklers that the staff would develop even more tactics to sell higher doses. They were using Purdue's data on thousands of doctors and patients to learn what made people willing to use high doses of opioids. They had started a study of physician characteristics and a "patient level analysis to determine what patient characteristics" were associated with "higher dose volume."

459. That same month, staff told the Sacklers that Purdue employed 637 sales reps and, during Q1 2013, they visited prescribers 155,354 times. Upon information and belief, many of those visits took place in Oklahoma, including in the 14 counties comprising the TJSA.

460. **In July**, the Sacklers discussed "threats" to their business from data on long-term opioid use, as public health authorities reacted to the danger of keeping patients on opioids for longer periods of time. Meanwhile, staff sent the Sacklers a "Flash Report" that OxyContin sales had dropped $96,400,000 from the year before. Staff explained to the Sacklers that insufficient volume of sales rep visits to promote OxyContin to prescribers was an important reason for the dropping sales. Staff told the Sacklers that they would increase the number of sales visits and had hired McKinsey to study how to get doctors to prescribe more OxyContin.

461. Staff also reported to the Sacklers that key priorities were to reverse "the decline in higher strengths" of Purdue opioids, and the decline in "tablets per Rx," which were reducing Purdue's profit. They told the Sacklers that Purdue staff were studying ways to fight these trends, and McKinsey would analyze the data down to the level of individual physicians.

462. Mortimer Sackler asked for more detail on what was being done to increase sales. Staff told the Sacklers that McKinsey would analyze whether sales reps were targeting the prescribers who were most susceptible to increasing opioid use. Staff told the Sacklers that McKinsey would study whether Purdue could use incentive compensation to push reps to

generate more prescriptions. Making the sales reps' income depend on increasing prescriptions could be a powerful lever. Staff told the Sacklers that McKinsey would study using "patient pushback" to get doctors to prescribe more opioids: When doctors hesitated to prescribe Purdue opioids, Purdue could get patients to lobby for the drugs. Staff told the Sacklers that McKinsey would also study techniques for keeping patients on opioids longer, including the need for sales reps "to make a lot of calls on physicians with a high number of continuing patients."

463. Staff also reported to the Sacklers that they had trained Purdue's sales reps to use new sales materials designed to get patients on higher doses of opioids for longer periods. Staff told the Sacklers that Purdue employed 634 sales reps and, during Q2 2013, they visited prescribers 177,773 times. Upon information and belief, many of those visits took place in Oklahoma, including in the 14 counties comprising the TJSA. Staff assured the Sacklers that they were trying to achieve even more sales visits by monitoring the reps.

464. Before the month ended, the Sacklers met to discuss a report on sales tactics that McKinsey had prepared for them – *Identifying Granular Growth Opportunities for OxyContin: First Board Update*. McKinsey confirmed that Purdue's sales visits generated opioid prescriptions. They urged the Sacklers to demand more sales visits from sales reps, increasing each rep's annual quota from 1,400 towards 1,700. McKinsey also advised the Sacklers to control the sales reps' target lists more strictly, to make reps visit doctors who give the biggest payoff. Based on a review of data, McKinsey also suggested that the Sacklers should have staff emphasize opioid savings cards in neighborhoods with high concentrations of Walgreens pharmacies. To allow even more targeted promotion of high doses, McKinsey asked the Sacklers to obtain "prescriber level milligram closing data" so they could analyze the doses prescribed by individual doctors.

465. Days later, staff told the Sacklers that Purdue paid their family $42,000,000.

466. In August, the Sacklers met to discuss a new McKinsey report on sales tactics: *Identifying Granular Growth Opportunities for OxyContin: Addendum to July 18th and August 5th Updates*. McKinsey recommended that the Sacklers immediately order a series of actions to increase sales. First, McKinsey urged the Sacklers to direct sales reps to the most prolific opioid prescribers. The consultants told the Sacklers that prescribers in the more prolific group write "25 times as many OxyContin scripts" as less prolific prescribers. They also reported to the Sacklers that sales rep visits to these prolific prescribers cause them to prescribe even more opioids: If Purdue ordered reps to focus on the most prolific prescribers, it could increase sales.

467. Second, McKinsey recommended that the Sacklers fight back against steps that the DEA, the U.S. Department of Justice, and others were taking to stop illegal drug sales. Two months earlier, the Walgreens pharmacy company admitted that it broke the law by filling illegitimate prescriptions, and it agreed to new safeguards to stop illegal prescribing. McKinsey told the Sacklers that "deep examination of Purdue's available pharmacy purchasing data shows that Walgreens has reduced its units by 18%." Even worse for the Sacklers, the new safeguards were hurting sales of the highest doses: "the Walgreens data also shows a significant impact on higher OxyContin dosages" – specifically the 80mg dose. McKinsey urged the Sacklers to lobby Walgreens' leaders to loosen up. For the longer term, McKinsey advised the Sacklers to develop a "direct-to-patient mail order" business for Purdue opioids, so they could sell the high doses without pharmacies getting in the way.

468. Third, McKinsey advised the Sacklers that they should use their power on the Board to insist on increasing sales, with monthly accountability: "Establish a revenue growth goal (*e.g.*, $150M incremental stretch goal by July 2014) and set monthly progress reviews with

CEO and Board." McKinsey knew what the Sacklers were looking for: They reported that "the value at stake is significant – hundreds of millions, not tens of millions." The consultants urged the Sacklers to make "a clear go-no go decision to 'Turbocharge the Sales Engine.'"

469. **In September and October**, the Sacklers met again to discuss implementation of the sales tactics McKinsey had recommended. The Sacklers discussed DEA efforts to stop illegal dispensing of opioids at CVS and Walgreens and how Purdue could get around the new safeguards by shifting to mail-order pharmacies, specialty pharmacies, or Purdue distributing opioids to patients directly.

470. Meanwhile, McKinsey kept reporting to Purdue on tactics to get more patients on higher doses of opioids. McKinsey found that Purdue could drive opioid prescriptions higher by targeting the highest-prescribing doctors and sending sales reps to visit each prolific prescriber dozens of times per year.

471. **In October**, Mortimer Sackler pressed for more information on dosing and "the breakdown of OxyContin market share by strength." Staff told the Sacklers that "the high dose prescriptions are declining," and "there are fewer patients titrating to the higher strengths from the lower ones." In response to the Sacklers' insistent questions, staff explained that sales of the highest doses were not keeping up with the Sacklers' expectations because some pharmacies had implemented "good faith dispensing" policies to double-check prescriptions that looked illegal and some prescribers were under pressure from the DEA. Staff promised to increase the budget for promoting OxyContin by $50,000,000, and to get sales reps to generate more prescriptions with a new initiative to be presented to the Sacklers the following week.

472. At the end of the month, the Sacklers met to discuss Purdue's budget for sales and marketing for 2014. Staff told the Sacklers (again) that Purdue's opioid savings cards kept

patients on opioids longer. Looking ahead at 2014, staff reported to the Sacklers that doctors shifting away from high doses and towards fewer pills per prescription could cost Purdue hundreds of millions of dollars in lost sales. To fight against that threat, staff told the Sacklers that they would increase the sales visits by each rep to 7.3 visits per day and visit prescribers 758,164 times in the year.

473. **In November**, Richard Sackler complained that he was getting too much information about the dangers of Purdue opioids. Richard had set up a Google alert to send him news about OxyContin, and he objected to a Purdue Vice President: "Why are all the alerts about negatives and not one about the positives of OxyContin tablets?" Staff immediately offered to replace Richard's alert with a service that provided more flattering stories.

474. Staff reported to the Sacklers that a key initiative during Q3 2013 was for sales reps to encourage doctors to prescribe OxyContin to elderly patients on Medicare. Upon information and belief, the sales reps did not disclose to doctors in Oklahoma and the TJSA that elderly patients faced greater risks of drug interactions, injuries, falls, and suffocating to death.

475. Staff also reported to the Sacklers that another key initiative during Q3 2013 was for sales reps to promote OxyContin for patients who had never taken opioids before. Upon information and belief, in Oklahoma and the TJSA during 2013, Purdue sales reps did not disclose to doctors that opioid-naive patients faced greater risks of overdose and death.

476. Staff also told the Sacklers that analysis conducted in July 2013 showed that opioid savings cards earned the Sacklers more money by keeping patients on opioids longer; specifically, more patients stayed on OxyContin longer than 60 days. Staff reported to the Sacklers that Purdue was pushing opioid savings cards in sales rep visits, through email to tens of thousands of health care providers, and online. Upon information and belief, in Oklahoma

and the TJSA during 2013, sales reps reported to Purdue that they promoted opioid savings cards to prescribers more than a thousand times. Upon information and belief, the sales reps did not tell doctors in Oklahoma and the TJSA that savings cards led patients to stay on opioids longer than 60 days, or that staying on opioids longer increased the risk of addiction and death.

477. Staff reported to the Sacklers that Purdue paid their family $399,920,000 through January through September 2013. But staff told the Sacklers that, from January to September 2013, Purdue lost hundreds of millions of dollars in profits because some prescribers were shifting away from higher doses of Purdue opioids.

478. Staff told the Sacklers that, in Q4 2013, sales reps would increase the number of visits to prescribers. Upon information and belief, many of those visits took place in Oklahoma, including in the 14 counties comprising the TJSA.

479. Staff also reported to the Sacklers that a key initiative in 2013 was to train sales reps to keep patients on Butrans opioids longer. They told the Sacklers that, at the same time as the initiative to keep patients on opioids longer, Purdue launched a new high dose of its Butrans opioid; sales reps began promoting the new high dose to physicians using new sales materials; and initial orders were double the company's forecasts. Staff reported to the Sacklers that marketing and sales activities generated 266,842 additional prescriptions and highlighted that opioid savings cards generate especially "high returns" by keeping patients on opioids longer.

480. Staff reported to the Sacklers that Purdue had sent more than 880,000 emails to health care professionals to promote its Butrans opioid, and posted online advertising seen more than 5 million times for Butrans and nearly 4 million times for OxyContin. They told the Sacklers that hundreds of thousands of communications to prescribers nationwide presented the

same "key selling messages" designed to get more patients on OxyContin at higher doses for longer periods of time, and specifically promoted Purdue's opioid savings cards.

481. Staff reported to the Sacklers that they were working with McKinsey to study ways to sell more OxyContin. Staff also reported that they had direct access to physician-level data to analyze prescriptions by individual doctors. Staff gave the Sacklers the latest results regarding how opioid savings cards led to patients staying on OxyContin longer.

482. Staff also reported results from Purdue's marketing through the OxyContin Physicians' Television Network. Staff told the Sacklers that it increased opioid prescriptions.

483. Staff also told the Sacklers that they would begin reviews of sales reps according to their sales ranking, with a focus on the bottom 10%. Staff reported to the Sacklers that Purdue employed 637 sales reps and, during Q3 2013, they visited prescribers 179,640 times. Upon information and belief, many of those visits took place in Oklahoma, including in the 14 counties comprising the TJSA.

484. **In December**, staff told Richard Sackler that Butrans sales were increasing, and they suspected the increase was caused by Purdue's improved targeting, in which sales reps visited the most susceptible prolific prescribers.

485. Meanwhile, staff contacted Richard Sackler because they were concerned that the company's "internal documents" could cause problems if investigations of the opioid crisis expanded. Early the next year, staff told Jonathan Sackler about the same concern. Jonathan studied collections of news reports and asked staff to assure him that journalists covering the opioid epidemic were not focused on the Sacklers.

✣ ✣ ✣ ***2014*** ✣ ✣ ✣

486. **In January 2014**, staff reported to the Sacklers on how Purdue's program for complying with state and federal law compared to recent agreements between other drug companies and the government. Other companies had agreed that sales reps should not be paid bonuses based on increasing doctors' prescriptions, but Purdue still paid reps for generating sales. Other companies disclosed to the public the money they spent to influence continuing medical education, but Purdue did not. Other companies had adopted "claw-back" policies so that executives would forfeit bonuses they earned from misconduct, but Purdue had not. The Boards of other companies passed resolutions each quarter certifying their oversight of the companies' compliance with the law, but the Sacklers did not.

487. **In February**, staff sent the Sacklers the final results from 2013. Staff told the Sacklers that net sales were hundreds of millions of dollars below budget because doctors were not prescribing enough of the highest doses of opioids and were including too few pills with each prescription, and sales reps were not visiting doctors enough. Sales VP Russell Gasdia wrote privately to a friend: "Our myopic focus on extended release opioids with abuse deterrent properties has not yielded the results people thought it would in the market. It's been hard to convince colleagues and the board that our success in this market is over."

488. To get higher sales, staff told the Sacklers that they had tightened the requirements for sales reps' pay: From now on, sales reps would lose bonus pay if they did not visit "high value" prescribers often enough.

489. A few days later, staff told the Sacklers that Purdue's marketing had an immense effect in driving opioid prescriptions: According to Purdue's analysis, its sales and marketing tactics generated an additional 560,036 prescriptions of OxyContin in 2012 and 2013.

Nevertheless, staff reported to the Sacklers that net sales for 2013 had been $377,000,000 less than budgeted. Staff again reported that Purdue was losing hundreds of millions of dollars in expected profits because prescribers were shifting away from higher doses of Purdue opioids and including fewer pills per prescription. Staff told the Sacklers that a "Key Initiative" was to get patients to "stay on therapy longer."

490. Staff also told the Sacklers that key sales priorities were again to encourage doctors to prescribe Purdue opioids for elderly patients and patients who had not taken opioids before. Staff reported to Sacklers again that sales reps were continuing the *Individualize the Dose* campaign. As the Sacklers knew, Purdue designed that campaign to encourage higher doses. Staff also told the Sacklers that Purdue's eMarketing campaign for OxyContin reached 84,250 health care providers during Q4 2013. Staff told the Sacklers that they found increasing compliance concerns with Purdue's speaker programs, in which the company paid doctors to promote Purdue opioids to other doctors.

491. Staff told the Sacklers that Purdue employed 632 sales reps and, during Q4 2013, they visited prescribers 176,227 times. Upon information and belief, many of those visits took place in Oklahoma, including in the 14 counties comprising the TJSA.

492. That February report was the last of its kind. After Q4 2013, Purdue abolished the detailed Quarterly Reports that had created a paper trail of targets for sales visits and been emailed among the Board and staff. In 2013, the City of Chicago served Purdue with a subpoena seeking internal documents about Purdue's marketing of opioids. That provoked a flurry of activity, including discussion among the Sacklers. Purdue fought the subpoena, and it was withdrawn. For 2014, Purdue decided to limit many of its official Board reports to numbers and

graphs, and relay other information orally. But the Sacklers continued to demand information about sales tactics, and their control of Purdue's deceptive marketing did not change.

493. **In March and April**, staff told the Sacklers that Purdue was achieving its goals of selling higher doses of OxyContin and more pills of OxyContin per prescription, but weekly prescriptions of Purdue's Butrans opioid were below expectations because of a reduced number of sales rep visits promoting that opioid. The Sacklers had assumed prescriptions would fall, but staff were concerned that the effect could be greater than anticipated.

494. **In May**, Raymond Sackler sent David, Jonathan, and Richard Sackler a confidential memo about Purdue's strategy, including specifically putting patients on high doses of opioids for long periods of time. The memo recounted that some physicians had argued that patients should not be given high doses of Purdue opioids, or kept on Purdue opioids for long periods of time, but Purdue had defeated efforts to impose a maximum dose limit or a maximum duration of use. Raymond asked David, Jonathan, and Richard to talk with him about the report.

495. **In June**, the Sacklers removed Russell Gasdia as Vice President of Sales and Marketing, and began pushing his replacement to sell more opioids faster. Gasdia warned his replacement that Richard managed the sales operation intensely – "there are times this becomes a tennis match with Dr. Richard." Sure enough, Richard told Gasdia's replacement that he would be given little time to show that he could increase opioid sales: "it is very late in the day to rescue the failed launch" of Butrans, which was not making as much money as Richard desired. CEO Mark Timney tried to caution Richard that it was "a little early" to be attacking the new sales leader, since he had been at Purdue only two weeks.

496. That same month, staff sent the Sacklers an "Update on *L.A. Times* mitigation effort" about tactics to discourage scrutiny of Purdue's misconduct. Staff wrote to the Sacklers:

> As you may recall, one of our efforts to mitigate the impact of a potential negative *Los Angeles Times* (LAT) story involved assisting a competing outlet in marginalizing the LAT's unbalanced coverage by reporting the facts before the LAT story ran. The following *Orange County Register* story, developed in close coordination with Purdue, achieved this goal. This fact- based narrative robs the LAT account of its newsworthiness and contradicts many of the claims we expected that paper to make.

In 2012, the *L.A. Times* had studied coroner's records and revealed that overdoses killed thousands of patients who were taking opioids prescribed by their doctors, refuting the Sacklers' lie that patients who are prescribed opioids do not get addicted and die. The next year, the *L.A. Times* revealed that Purdue tracked illegal sales of OxyContin with a secret list of 1,800 doctors code-named *Region Zero*, but did not report them to the authorities. The "mitigation effort" that the Sacklers ordered was not designed to protect patients from overdoses or from illegal prescribers, but instead to protect the Sacklers from reporters revealing the truth.

497. **In July**, Richard Sackler called staff to complain about studies that the FDA required for opioids and how they might undermine Purdue's sales. He emphasized that Purdue Board members felt the requirements to conduct studies were unfair. Staff tried to reassure Richard that the studies would take "several years to complete, thereby keeping our critics somewhat at-bay during this time."

498. **In July** and again in **August**, **September**, and **October**, staff warned the Sacklers that two of the greatest risks to Purdue's business were "[c]ontinued pressure against higher doses of opioids," and "[c]ontinued pressure against long term use of opioids."

RISKS

i. Continued pressure against higher doses of opioids,

ii. Continued pressure against long term use of opioids,

Staff report to the Board on risks facing Purdue's business

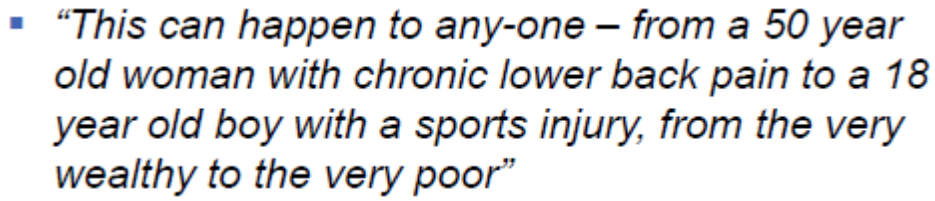
Staff told the Sacklers that Purdue's #1 opportunity to resist that pressure was by sending sales reps to visit prescribers; and, specifically, by targeting the most susceptible doctors, who could be convinced to be prolific prescribers, and visiting them many times.

✣ ✣ ✣ ***Project Tango*** ✣ ✣ ✣

499. **In September 2014**, Kathe Sackler dialed in to a confidential call about *Project Tango*. *Project Tango* was a secret plan for Purdue to expand into the business of selling drugs to treat opioid addiction. In their internal documents, Kathe and staff wrote down what Purdue publicly denied for decades: that addictive opioids and opioid addiction are "naturally linked." They determined that Purdue should expand across "the pain and addiction spectrum," to become "an end-to-end pain provider." Purdue illustrated the end-to-end business model with a picture of a dark hole labeled "Pain treatment" that a patient could fall into – and "Opioid addiction treatment" waiting at the bottom.

500. Kathe Sackler and the *Project Tango* team reviewed their findings that the "market" of people addicted to opioids, measured coldly in billions of dollars, had doubled from 2009 to 2014. Kathe and the staff found that the catastrophe provided an excellent compound annual growth rate ("CAGR"): "Opioid addiction (other than heroin) has grown by ~20% CAGR from 2000 to 2010."

501. Kathe Sackler and the staff revealed in their internal documents that Purdue's tactic of blaming addiction on untrustworthy patients was a lie. Instead, the truth is that opioid addiction can happen to anyone who is prescribed opioids:



Purdue's "Project Tango" patient and clinical rationale

Kathe and the staff concluded that millions of people who became addicted to opioids were the Sacklers' next business opportunity. Staff wrote: "It is an attractive market. Large unmet need for vulnerable, underserved and stigmatized patient population suffering from substance abuse, dependence and addiction." The team identified eight ways that Purdue's experience getting patients on opioids could now be used to sell treatment for opioid addiction.

502. Kathe Sackler instructed staff that *Project Tango* required their "immediate attention." She pressed staff to look into reports of children requiring hospitalization after swallowing buprenorphine – the active ingredient in Purdue's Butrans opioid and the opioid addiction treatment that the Sacklers wanted to sell in a film that melts in the user's mouth. Staff assured Kathe that children were overdosing on pills, not medicinal films, "which is a positive for *Tango*."

503. **In February 2015**, staff presented Kathe Sackler's work on *Project Tango* to the Board. The plan was for a Joint Venture controlled by the Sacklers to sell the addiction medication suboxone.

504. The *Tango* team mapped how patients could get addicted to opioids through prescription opioid analgesics such as Purdue's OxyContin or heroin, and then become consumers of the new company's suboxone. The team noted the opportunity to capture customers: Even after patients were done buying suboxone the first time, 40-60% would relapse and need it again.

505. The next month, *Project Tango* came to an end. Kathe, David, Jonathan, and Mortimer Sackler discussed the discontinuation of the project at their Business Development Committee meeting. But the Sackler's efforts to sell addictive opioids continued.

506. **In October 2014**, staff sent the Sacklers a Proposed Operating Plan and Budget to be approved by the Board for 2015. Staff told the Sacklers that a key tactic for 2015 would be to convert patients from short-acting opioids to OxyContin. Staff warned the Sacklers that prescribers were shifting away from the highest doses of Purdue's opioids, and toward fewer pills per prescription, and those shifts would cost Purdue $99,000,000 a year. Staff told the Sacklers that a key tactic to increase Butrans sales in 2015 would be for Purdue sales reps to push doctors to "titrate up" to higher doses. Staff likewise told the Sacklers that visits to doctors by sales reps would be a key tactic to launch Purdue's new Hysingla opioid: the company would: "[l]everage Purdue's existing, experienced sales force to drive uptake with target HCPs" and "[a]dd additional contract sales force capacity at launch to drive uptake." Staff proposed that Purdue employ 519 sales reps, paid an average salary of $81,300 plus a bonus of up to an additional $124,600 based on sales.

507. Meanwhile, sales staff exchanged news reports of a lawsuit accusing Purdue of deceptive marketing in Kentucky. They quoted Purdue's own attorney and Chief Financial Officer stating that the company faced claims of more than a billion dollars that "would have a

crippling effect on Purdue's operations and jeopardize Purdue's long-term viability." Purdue's communications staff were delighted by the article, because it did not reveal the Sacklers' role in the misconduct. "I'm quite pleased with where we ended up. There's almost nothing on the Sacklers and what is there is minimal and buried in the back."

508. **In November**, staff reported to the Sacklers that their sales tactics were working, and the shift away from higher doses of OxyContin had slowed.

509. **In December**, staff told the Sacklers that Purdue would pay their family $163,000,000 in 2014 and projected $350,000,000 in 2015.

510. On New Year's Eve, Richard Sackler told staff that he was starting a confidential sales and marketing project on opioid prices and instructed them to meet with him about it on January 2.

✣ ✣ ✣ ***2015*** ✣ ✣ ✣

511. Early in the morning of **January 2**, staff began scrambling to collect sales data for Richard Sackler. They didn't move quickly enough. Days later, Richard demanded a meeting with sales staff to go over plans for selling the highest doses. Richard asked for an exhaustive examination to be completed within 5 days, including:

> unit projections by strength, mg by strength . . . pricing expectations by strength . . . individual strength's market totals and our share going backward to 2011 or 12 and then forward to 2019 or 2020 . . . the same information for Hysingla . . . [and] the history of OxyContin tablets from launch to the present.

The CEO stepped in to say the work would take 3 weeks. Richard let him know that wasn't a great response – "That's longer than I had hoped for" – and directed marketing staff to start sending him materials immediately.

512. That same month, the Sacklers voted to evaluate employees' 2014 performance on a scorecard that assigned the greatest value to the volume of Purdue opioid sales. Employees were expected to generate more than $1.5 billion. The Sacklers also voted to establish the company's scorecard for 2015: Once again, the biggest factor determining employees' payout would be the total amount of Purdue opioid sales.

513. **In April**, staff told the Sacklers that sales of Purdue's highest dose 80mg OxyContin were down 20% and that the average prescription had declined by eight pills since 2011.

514. The Sacklers voted to expand the sales force by adding another 122 reps. As with every reference to "the Sacklers" after July 2012, that includes Beverly, David, Ilene, Jonathan, Kathe, Mortimer, Richard, and Theresa Sackler.

515. Staff told the Sacklers the additional reps would increase net sales of opioids by $59,000,000.

516. The Sacklers knew and intended that, because of their vote, more sales reps would promote opioids to prescribers in Oklahoma, including in the 14 counties composing the TJSA.

517. **In October**, Purdue executives identified avoiding investigations of Purdue's opioid marketing as a "Key Activity" in the company's Operational Plan.

518. **In November**, the Sacklers voted on the budget for Purdue for 2016. Staff warned the Sacklers that public concern about opioids could get in the way of Purdue's. Staff again told the Sacklers that two of the most significant challenges to Purdue's plans were doctors not prescribing enough of the highest strength opioids and including too few pills in each prescription. Staff told the Sacklers that declining prescriptions of the highest doses and fewer pills per prescription would cost Purdue $77,000,000.

519. Staff proposed to the Sacklers that, for 2016, Purdue would plan for prescribers to average 60 pills of Purdue opioids per prescription. They told the Sacklers that they would aim to make enough of those pills be high doses to make the average per pill 33 milligrams of oxycodone. That way, Purdue could hit its target for the total kilograms of oxycodone it wanted to sell.

520. To make sure Purdue hit the targets, staff told the Sacklers that sales reps were visiting prescribers 21% more often than before. Staff told the Sacklers that they had aggressively reviewed and terminated reps who failed to generate prescriptions. Staff reported to the Sacklers that, in 2015 alone, Purdue replaced 14% of its sales reps and 20% of its District Managers for failing to create enough opioid sales.

521. Looking ahead, staff told the Sacklers that "the 2016 investment strategy focuses on expanding the Sales Force." They reported that the proposed budget for sales and promotion was $11,600,000 higher than 2015, "primarily due to the Sales Force expansion." The top priority for the sales reps would be to visit the highest-prescribing doctors again and again. Staff proposed to the Sacklers that the #1 overall priority for 2016 would be to sell OxyContin through "disproportionate focus on key customers." They told the Sacklers that sales reps would also target prescribers with the lowest levels of training, physician's assistants and nurse practitioners, because they were "the only growing segment" in the opioid market. Purdue executives expected that, each quarter, the sales reps would visit prescribers more than 200,000 times and would get 40,000 new patients onto Purdue opioids.

522. **In December**, staff prepared to address wide-ranging concerns raised by the Sacklers. Kathe and Mortimer Sackler wanted staff to break out productivity data by indication versus prescriber specialty for each drug. Richard Sackler sought details on how staff was

calculating 2016 mg/tablet trends. Jonathan Sackler sought a follow-up briefing on how public health efforts to prevent opioid addiction would affect OxyContin sales.

523. Before the year ended, the Sacklers were invited to a "Beneficiaries Meeting" where Purdue staff reported to Sackler family members about the company's efforts to sell opioids.

✣ ✣ ✣ ***2016*** ✣ ✣ ✣

524. **In 2016**, the Sacklers met with the Board in January, March, April, June, August, October, November, and December.

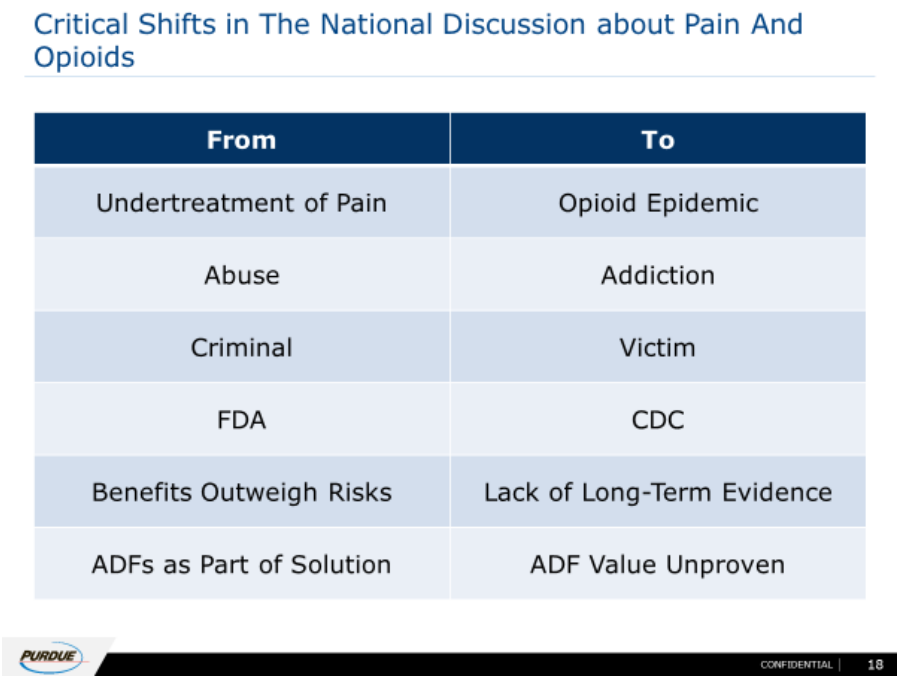
525. **In April**, the Sacklers considered exactly how much money was riding on their strategy of pushing higher doses of opioids. The month before, the U.S. Centers for Disease Control announced guidelines to try to slow the epidemic of opioid overdose and death. The CDC urged prescribers to avoid doses higher than 30mg of Purdue's OxyContin twice per day. The CDC discouraged twice-a-day prescriptions of all three of Purdue's most profitable strengths – 40mg, 60mg, and 80mg.

526. **In May**, Richard Sackler told staff to circulate a *New York Times* story reporting that opioid prescriptions were dropping for the first time since Purdue launched OxyContin twenty years earlier. The *Times* wrote: "Experts say the drop is an important early signal that the long-running prescription opioid epidemic may be peaking, that doctors have begun heeding a drumbeat of warnings about the highly addictive nature of the drugs." The only person quoted in favor of *more* opioid prescribing was a Massachusetts professor whose program at Tufts University was funded by the Sacklers.

527. **In June**, the Sacklers met to discuss a revised version of *Project Tango* – another try at profiting from the opioid crisis. This time, they considered a scheme to sell the overdose

antidote NARCAN. The need for NARCAN to reverse overdoses was rising so fast that the Sacklers calculated it could provide a growing source of revenue, tripling from 2016 to 2018. Like *Tango*, Purdue's analysis of the market for NARCAN confirmed that they saw the opioid epidemic as a money-making opportunity and that the Sacklers understood – in private, when no one was watching – how Purdue's opioids put patients at risk. The Sacklers identified a "strategic fit" because NARCAN is a "complementary" product to Purdue opioids. They specifically identified patients on Purdue's prescription opioids as the target market for NARCAN. Their plan called for studying "***long-term scrip users***" to "better understand target end-patients" for NARCAN. Likewise, they identified the same doctors who prescribed the most Purdue opioids as the best market for selling the overdose antidote; they planned to "leverage the current Purdue sales force" to "drive direct promotion to targeted opioid prescribers." Finally, they noted that Purdue could profit from government efforts to use NARCAN to save lives.

528. That same month, staff presented the 2016 Mid-Year Update. They warned the Sacklers that shifts in the national discussion of opioids threatened their plans. The deception that Purdue had used to conceal the risks of opioids was being exposed. Staff summarized the problems on a slide:



Critical Shifts in The National Discussion about Pain And Opioids

From	To
Undertreatment of Pain	Opioid Epidemic
Abuse	Addiction
Criminal	Victim
FDA	CDC
Benefits Outweigh Risks	Lack of Long-Term Evidence
ADFs as Part of Solution	ADF Value Unproven

PURDUE CONFIDENTIAL | 18

529. *First*, to convince doctors to prescribe dangerous opioids, Purdue promoted its drugs as the solution to "undertreatment of pain." Richard Sackler made sure that Purdue bought the internet address 5thvitalsign.com so it could promote pain as the "fifth vital sign" (along with temperature, blood pressure, pulse, and breathing rate) to expand the market for opioids. But now, staff reported to the Sacklers, doctors and patients were starting to worry more about the epidemic of opioid addiction and death.

530. *Second*, to conceal the danger of addiction, Purdue falsely blamed the terrible consequences of opioids on drug abuse. One of Purdue's key messages argued: "It's not

addiction, it's abuse." But now, staff reported to the Sacklers, doctors and patients were realizing that *addiction* was a true danger.

531. *Third*, to avoid responsibility for Purdue's dangerous drugs, the Sacklers chose to stigmatize people who were hurt by opioids, calling them "junkies" and "criminals." Richard Sackler wrote that Purdue should "hammer" them in every way possible. But now, staff reported to the Sacklers, Americans were seeing through the stigma and recognizing that millions of families were victims of addictive drugs. Staff told the Sacklers that nearly half of Americans reported that they knew someone who had been addicted to prescription opioids.

532. *Fourth*, the Sacklers had long sought to hide behind the approval of Purdue's drugs by the FDA. But FDA approval could not protect the Sacklers when their deceptive marketing led thousands of patients to become addicted and die. The U.S. Centers for Disease Control ("CDC") reported that opioids were, indeed, killing people. The CDC Director said: "We know of no other medication that's routinely used for a nonfatal condition that kills patients so frequently." The 2016 Mid-Year Update warned that the truth was threatening Purdue.

533. In the face of this pressure, staff told the Sacklers that the sales team was focusing on the doctors who prescribe the most opioids.

534. **In November**, staff prepared statements to the press denying the Sacklers' involvement in Purdue. Their draft claimed: "Sackler family members hold no leadership roles in the companies owned by the family trust." That was a lie. Sackler family members held the controlling majority of seats on the Board and, in fact, controlled the company. A staff member reviewing the draft knew what was up and commented with apparent sarcasm: "Love the . . . statement." Staff eventually told the press: "Sackler family members hold no management positions."

535. Some employees worried about the deception. When journalists asked follow-up questions about the Sacklers, communications staff deliberated about whether to repeat the "no management positions" claim. They double-checked that Purdue's top lawyers had ordered the statement. Then they arranged for one of the Sacklers' foreign companies to issue it, so U.S. employees would not be blamed: "The statement will come out of Singapore."

536. **In December**, Richard, Jonathan, and Mortimer Sackler had a call with staff about another revised version of *Project Tango*. The new idea was to buy a company that treated opioid addiction with implantable drug pumps. The business was a "strategic fit," because Purdue sold opioids and the new business treated the "strategically adjacent indication of opioid dependence." The Sacklers kept searching for a way to expand their business by selling both addictive opioids and treatment for opioid addiction.

✣ ✣ ✣ ***2017*** ✣ ✣ ✣

537. **In 2017**, the Sacklers met with the Board in February, March, April, June, July, August, October, November, and December.

538. **In May 2017**, staff told the Sacklers that an independent nonprofit had concluded that Purdue's reformulation of OxyContin was not a cost-effective way to prevent opioid abuse. Theresa Sackler asked staff what they were doing to fight back to convince doctors and patients to keep using the drug.

539. That same month the Sacklers were looking for a new CEO. Long-time employee Craig Landau wanted the job and prepared a business plan titled "SACKLER PHARMA ENTERPRISE." Landau was careful to acknowledge their power: he acknowledged that Purdue operated with "the Board of Directors serving as the 'de facto' CEO." He proposed that Purdue should take advantage of other companies' concerns about the opioid epidemic through an

"opioid consolidation strategy" and become an even more dominant opioid seller "as other companies abandon the space." The Sacklers made him CEO a few weeks later.

540. **In June**, staff told the Sacklers that getting doctors to prescribe high doses of opioids and many pills per prescription were still key "drivers" of Purdue's profit. Purdue's management was concerned that the CDC's efforts to save lives by reducing doses and pill counts would force the company "to adjust down our revenue expectations."

541. Staff told the Sacklers that Purdue's opioid sales were being hurt by cultural trends such as the HBO documentary, "*Warning: This Drug May Kill You*." HBO's film was a problem for Purdue because it showed actual footage from Purdue's misleading advertisements next to video of people who overdosed and died.

542. Staff felt the pressure of the opioid epidemic, even if the billionaire Sacklers did not. In one presentation, staff came close to insubordination and told the Sacklers: "Purdue Needs a New Approach." Their suggestion for a new direction was: "A New Narrative: Appropriate Use." The Sacklers led Purdue so far into the darkness that employees proposed "appropriate use" of drugs to reinvent the company. Staff also suggested that the Sacklers create a family foundation to help solve the opioid crisis.

543. The Sacklers did not redirect the company toward appropriate use or create the suggested family foundation. Instead, they decided to sell harder. For 2018, the Sacklers approved a target for sales reps to visit prescribers 1,050,000 times – almost double the number of sales visits they had ordered during the heyday of OxyContin in 2010.

544. On October 17, Beverly Sackler served her last day on the Board. It was the beginning of the end for the Sackler family. A week later, the *New Yorker* published an article entitled "The Family That Built an Empire of Pain." The story quoted a former FDA

Commissioner: "the goal should have been to sell the least dose of the drug to the smallest number of patients." The reporter concluded: "Purdue set out to do exactly the opposite."

545. **In November**, Jonathan Sackler suggested that Purdue launch yet another opioid. Staff promised to present a plan for additional opioids at the next meeting of the Board. At the Board meeting that month, the remaining Sackler Board members (Richard, David, Ilene, Jonathan, Kathe, Mortimer, and Theresa) voted to cut the sales force from 582 reps to 302 reps.

✣ ✣ ✣ ***2018*** ✣ ✣ ✣

546. **In January 2018**, Richard Sackler received a patent for a drug to treat opioid addiction – his own version of *Project Tango*. Richard had applied for the patent in 2007. He assigned it to a different company controlled by the Sackler family, instead of Purdue. Richard's patent application says opioids *are* addictive. The application calls the people who become addicted to opioids "junkies" and asks for a monopoly on a method of treating addiction.

547. In January, Richard Sackler also met with Purdue staff about the sales force again. They discussed plans to cut the force to 275 reps. In February, Richard, David, Ilene, Jonathan, Kathe, Mortimer, and Theresa Sackler decided to lay off 300 sales reps.

548. **By April**, staff were scared. Richard Sackler was again asking questions about sales. Staff prepared a presentation for the Board. One employee suggested that they add more information about the company's problems. Another cautioned against that:

> I think we need to find a balance between being clear about what reality looks like – which I certainly support in [this] situation – and just giving so much bad news about the future that it just makes things look hopeless. Let's not give the [Board] a reason to just walk away.

549. **On May 3** and again on **June 6 and 8**, all seven remaining Sacklers attended meetings of the Board: Richard, David, Ilene, Jonathan, Kathe, Mortimer, and Theresa.

550. As lawsuits began to be filed, and just as their employees predicted, the Sacklers tried to run. Richard Sackler was the first to go: he resigned from the Board in July. David Sackler quit in August. Theresa Sackler served her last day in September. As of December 2018, Ilene, Jonathan, Kathe, and Mortimer remain.

CLAIMS

ILLEGAL MARKETING – COUNT ONE
Violation of the Cherokee Nation Unfair and Deceptive Practices Act Title 12 § 25

551. The Cherokee Nation re-alleges and incorporates by reference paragraphs 1-544.

552. The Cherokee Attorney General is entitled to bring a suit on behalf of the Cherokee Nation or its citizens to enforce Cherokee consumer protection laws and to collect up to $10,000 for each violation.

553. Section 25 of the Cherokee Nation Unfair and Deceptive Trade Practices Act ("CNUDPA") prohibits deceptive acts or practices in the conduct of any trade or commerce.

554. Defendants committed a prohibited act in the course of trade when they instructed to be introduced or introduced misbranded drugs, including OxyContin and other opioid drugs, into interstate commerce in violation of sections of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 331(a), 352(a), (j), (n), 333(a)(2)).

555. By violating the Federal Food, Drug, and Cosmetic Act, Defendants are liable under §§ 25(A) and (B)(25) of the CNUDPA, which makes it a civil offense to violate federal statutes affecting or impacting consumer goods, which by definition include any tangible chattels bought for medical purposes.

556. Defendants nevertheless continue to instruct to introduce or introduce misbranded drugs and deceptively market opioid drugs. That conduct amounts to an unfair, deceptive, unscrupulous, and immoral trade practice that is against public policy, in violation of § 25 of the CNUDPA.

ILLEGAL MARKETING – COUNT TWO
Violation of the Cherokee Nation Unfair and Deceptive Practices Act Title 12 § 25

557. The Cherokee Nation re-alleges and incorporates by reference paragraphs 1- 544.

558. The Cherokee Attorney General is entitled to bring a suit on behalf of the Cherokee Nation or its citizens to enforce Cherokee consumer protection laws and to collect up to $10,000 for each violation.

559. Section 25 of the CNUDPA prohibits deceptive acts or practices in the conduct of any trade or commerce.

560. Defendants committed prohibited acts in the course of trade by "[r]epresenting that [OxyContin and other opioid drugs marketed by Defendants had] characteristics, ingredients, uses, benefits, or quantities which they do not have," in violation of CNUDPA § 25(B)(5), and by "[f]ailing to adequately warn or instruct of the potential risks, side effects, or allergic reactions that the manufacturer or distributor knew or reasonably should have known about," in violation of CNUDPA § 25(B)(24).

ILLEGAL MARKETING – COUNT THREE
Violation of the Cherokee Nation Unfair and Deceptive Practices Act Title 12 § 26

561. The Cherokee Nation re-alleges and incorporates by reference paragraphs 1- 544.

562. The Cherokee Attorney General is entitled to bring a suit on behalf of the Cherokee Nation or its citizens to enforce Cherokee consumer protection laws and to collect up to $10,000 for each violation.

563. Section 26 of the CNUDPA makes it unlawful for any individual or entity "to make or disseminate or cause to be made or disseminated before in the Cherokee Nation, . . . in any newspaper or other publication, or any advertising device, . . . any statement, concerning that product, . . . which is untrue or misleading, which fails to adequately warn, or which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading."

564. Defendants caused untrue and misleading statements which failed to adequately warn about the dangers of OxyContin and other opioid drugs to be disseminated in the Cherokee

Nation when they knew or should have known the statements were untrue, misleading, and failed to adequately warn about the dangers of opioids – specifically, their highly addictive and destructive nature – despite the fact that Defendants knew or should have known their statements were unfair and misleading.

ILLEGAL MARKETING – COUNT FOUR
Violation of the Oklahoma Consumer Protection Act

565. The Cherokee Nation re-alleges and incorporates by reference paragraphs 1- 544.

566. The Oklahoma Consumer Protection Act ("OCPA") forbids any company from making a "false representation, knowingly or with reason to know, as to the characteristics, ingredients, uses, benefits, alterations, or quantities" of a consumer product. 15 Okla. Stat. Ann. § 753(5).

567. The OCPA also outlaws any "[u]nfair trade practice," which includes "any practice which . . . is immoral, unethical, oppressive, unscrupulous or substantially injurious to consumers." 15 Okla. Stat. Ann. § 752(14).

568. Under the OCPA, violators are "liable to the aggrieved consumer for the payment of actual damages sustained by the customer and costs of litigation including reasonable attorney's fees, and the aggrieved consumer shall have a private right of action for damages, including but not limited to, costs and attorney's fees." 15 Okla. Stat. Ann. § 761.1(A).

569. Defendants knowingly represented that OxyContin and other opioid drugs marketed by Defendants had "characteristics, ingredients, uses, benefits, alterations, or quantities" which they do not have, in violation of 15 Okla. Stat. Ann. § 753(5).

570. Defendants also knowingly failed to adequately warn or instruct of the potential risks and side effects – including addiction – of OxyContin and other opioid drugs, in violation of 15 Okla. Stat. Ann. § 752(14).

ILLEGAL MARKETING – COUNT FIVE
Fraud

571. The Cherokee Nation re-alleges and incorporates by reference paragraphs 1- 544.

572. Defendants, individually and acting through their employees and agents, made misrepresentations and omissions of facts material to the Cherokee Nation and its residents to induce them to purchase, administer, and consume opioids as set forth in detail below.

573. Defendants knew at the time that they made their misrepresentations and omissions that they were false but nevertheless continued to market and advertise highly addictive opioids to residents of the Cherokee Nation, who relied on the information provided by Defendants.

574. Defendants intended the Cherokee Nation and its residents to rely on their misrepresentations and omissions so that they might continue to turn a profit.

575. The Cherokee Nation reasonably relied on Defendants' misrepresentations and omissions as information promulgated by a pharmaceutical company with a legal duty to provide truthful information about OxyContin and other opioid drugs.

576. By reason of their reliance on Defendants' misrepresentations and omissions of material fact, the Cherokee Nation and its residents suffered actual financial damage. The Cherokee Nation has been forced to devote more of its resources to addiction-related problems, thereby leaving a diminished pool of available resources to other societal concerns, such as education and cultural preservation.

577. Defendants' conduct in knowingly and intentionally marketing OxyContin and other opioid drugs in a deceptive and unfair manner was willful, wanton, and malicious and was directed at the public generally.

ILLEGAL MARKETING – COUNT SIX
Nuisance

578. The Cherokee Nation re-alleges and incorporates by reference paragraphs 1- 544.

579. Defendants unreasonably and significantly interfered with the Cherokee Nation's public health, safety, peace, and public comfort through their role in deceptively and improperly marketing and promoting opioid drugs, which has resulted in high rates of addiction, overdoses, and injuries threatening the fabric of Cherokee society long term. Defendants' unreasonable conduct violates regulations and professional guidelines, in addition to their legally prescribed duties regarding accurate branding and marketing of their drugs under the Federal Food, Drug, and Cosmetics Act.

580. Defendants were unreasonable in their continued marketing, manufacturing, and distribution of opioids. Defendants' conduct has substantially impacted the well-being of the Cherokee Nation in the short term as well as for many generations to come, as the youngest Cherokee members have been particularly impacted by the opioid epidemic.

581. Defendants' conduct directly and proximately caused injury to the Cherokee Nation and its citizens.

ILLEGAL MARKETING – COUNT SEVEN
Negligence/Gross Negligence

582. The Cherokee Nation re-alleges and incorporates by reference paragraphs 1- 544.

583. Defendants negligently marketed and misbranded opioids in violation of their duty pursuant to the Federal Food, Drug, and Cosmetic Act by producing and disseminating misleading and deceptive advertising about the risks and dangers of OxyContin and other opioid drugs, which created a foreseeable injury to the Cherokee Nation by threatening the health, safety, and welfare of the Cherokee Nation and its citizens.

584. Defendants were also negligent *per se* based upon their violations of the Federal Food, Drug, and Cosmetic Act by introducing misbranded drugs, including OxyContin and other opioid drugs, into interstate commerce.

585. Defendants' negligent conduct was the direct and proximate cause of injury to the Cherokee Nation and its citizens.

586. Defendants' negligent conduct damaged the Cherokee Nation and its citizens, including damages to the health, safety, and welfare of the Cherokee Nation and its citizens.

ILLEGAL MARKETING – COUNT EIGHT
Unjust Enrichment

587. The Cherokee Nation re-alleges and incorporates by reference paragraphs 1- 544.

588. As an expected and intended result of Defendants' wrongdoing, they have profited and benefited from saturating Cherokee Nation society with highly addictive opioid painkillers that have been deceptively and unfairly marketed to the Cherokee Nation and its citizens, and which have caused injury to the Cherokee Nation.

589. Defendants have been unjustly enriched at the expense of the Cherokee Nation.

ILLEGAL MARKETING – COUNT NINE
Civil Conspiracy

590. The Cherokee Nation re-alleges and incorporates by reference paragraphs 1- 544.

591. Defendants (1) associated with one or more persons to further an unlawful objective, including deceptive and unfair marketing of opioid drugs, via an agreement, understanding, or "meeting of the minds" regarding the objective and the means of pursuing it; (2) committed an unlawful act in furtherance of the agreement; and (3) proximately caused harm as a result of their actions.

OPIOID DIVERSION – COUNT TEN
Violation of the Cherokee Nation Unfair and Deceptive Practices Act Title 12 § 25

592. The Cherokee Nation re-alleges and incorporates by reference paragraphs 1- 544.

593. The Cherokee Attorney General is entitled to bring a suit on behalf of the Cherokee Nation or its citizens to enforce Cherokee consumer protection laws and to collect up to $10,000 for each violation.

594. Section 25 of the Cherokee Nation Unfair and Deceptive Trade Practices Act ("CNUDPA") prohibits deceptive acts or practices in the conduct of any trade or commerce.

595. Defendants committed a prohibited act in the course of trade when it violated the Controlled Substances Act and its implementing regulations by manufacturing and distributing commonly abused and diverted opioids in such quantities that they knew or should have known these drugs were not ultimately being distributed for legitimate medical purposes.

596. By violating the Controlled Substance Act, Defendants are liable under the Cherokee Nation Unfair and Deceptive Trade Practices Act, which makes it a civil offense to violate federal statutes affecting chattels bought for medical purposes.

597. Defendants' underlying conduct in nevertheless continuing to manufacture and distribute the opioids constitutes an unfair, deceptive, unscrupulous, and immoral trade practice that is against public policy, in violation of § 25 of the CNUDPA.

OPIOID DIVERSION – COUNT ELEVEN
Fraud

598. The Cherokee Nation re-alleges and incorporates by reference paragraphs 1- 544.

599. Defendants, individually and acting through their employees and agents, made misrepresentations and omissions of facts material to the Cherokee Nation and its residents to induce them to purchase, administer, and consume opioids as set forth in detail below.

600. Defendants knew at the time that they made their misrepresentations and omissions that they were false but nevertheless continued to supply highly addictive opioids to the Cherokee Nation, who relied on the information provided by Defendants.

601. Defendants intended that the Cherokee Nation and its residents would rely on their misrepresentations and omissions so that they might continue to turn a profit, although they knew or should have known that the excessive quantities of opioid products shipped into the TJSA oversaturated the market and lead to illegal diversion.

602. The Cherokee Nation reasonably relied on Defendants' misrepresentations and omissions as information promulgated by a supposedly reputable pharmaceutical company with a legal duty to provide truthful information.

603. By reason of their reliance on Defendants' misrepresentations and omissions of material fact, the Cherokee Nation and its residents suffered actual pecuniary damage. The Cherokee Nation has been forced to devote more of its resources to addiction-related problems, thereby leaving a diminished pool of available resources to other societal concerns, such as education and cultural preservation.

604. Defendants' conduct in oversaturating the market with opioids and causing diversion through its failure to acknowledge numerous "red flags" pointing toward suspicious opioid orders being filled at an alarming rate was willful, wanton, and malicious and was directed at the public generally.

OPIOID DIVERSION – COUNT TWELVE
Nuisance

605. The Cherokee Nation re-alleges and incorporates by reference paragraphs 1- 544.

606. Defendants unreasonably and significantly interfered with the Cherokee Nation's public health, safety, peace, and public comfort through their role in diverting, selling, and

manufacturing opioids, which has resulted in high rates of addiction, overdoses, and injuries threatening the fabric of Cherokee society long term; Defendants' unreasonable conduct violates regulations and professional guidelines, in addition to their legally prescribed duty under the Controlled Substances Act.

607. Given the widespread acknowledgement of the opioid epidemic, suffered acutely by the Cherokee Nation, Defendants were unreasonable in their continued manufacture and distribution of opioids. Defendants' conduct has substantially impacted the well-being of the Cherokee Nation in the short term as well as for many generations to come, as the youngest Cherokee members have been particularly impacted by the opioid epidemic.

608. Defendants' conduct directly and proximately caused injury to the Cherokee Nation and its citizens.

OPIOID DIVERSION – COUNT THIRTEEN
Negligence/Gross Negligence

609. The Cherokee Nation re-alleges and incorporates by reference paragraphs 1- 544.

610. Defendants negligently facilitated the diversion of opioids in violation of their duty pursuant to the Controlled Substances Act by ignoring numerous "red flags" when it failed to exercise adequate control over the production, distribution, and sale of opioids, which created a foreseeable injury to the Cherokee Nation by threatening the health, safety, and welfare of the Cherokee Nation and its citizens.

OPIOID DIVERSION – COUNT FOURTEEN
Unjust Enrichment

611. The Cherokee Nation re-alleges and incorporates by reference paragraphs 1- 544.

612. As an expected and intended result of Defendants' wrongdoing, they have profited and benefited from saturating Cherokee Nation society with highly addictive opioid

painkillers diverted from their supply chain which the Cherokee Nation has paid for at an alarming rate.

613. Defendants have been unjustly enriched at the expense of the Cherokee Nation.

OPIOID DIVERSION – COUNT FIFTEEN

Civil Conspiracy

614. The Cherokee Nation re-alleges and incorporates by reference paragraphs 1- 544.

615. Defendants (1) associated with one or more persons to further an unlawful objective, including diversion of opioid drugs for non-medical purposes from the regulated controlled substances supply chain, via an agreement, understanding, or "meeting of the minds" regarding the objective and the means of pursuing it; (2) committed an unlawful act in furtherance of the agreement; and (3) proximately caused harm as a result of their actions.

PRAYER FOR RELIEF

WHEREFORE, the Cherokee Nation prays that the Court grant the following relief:

(a) Injunctive relief;

(b) Civil penalties;

(c) Compensatory damages;

(d) Restitution;

(e) Punitive damages;

(f) Attorneys' fees and costs; and

(g) All such other relief this Court deems just and fair;

(h) Plaintiff seeks a trial by jury for all counts so triable.

DATED: August 12, 2019

Respectfully Submitted,

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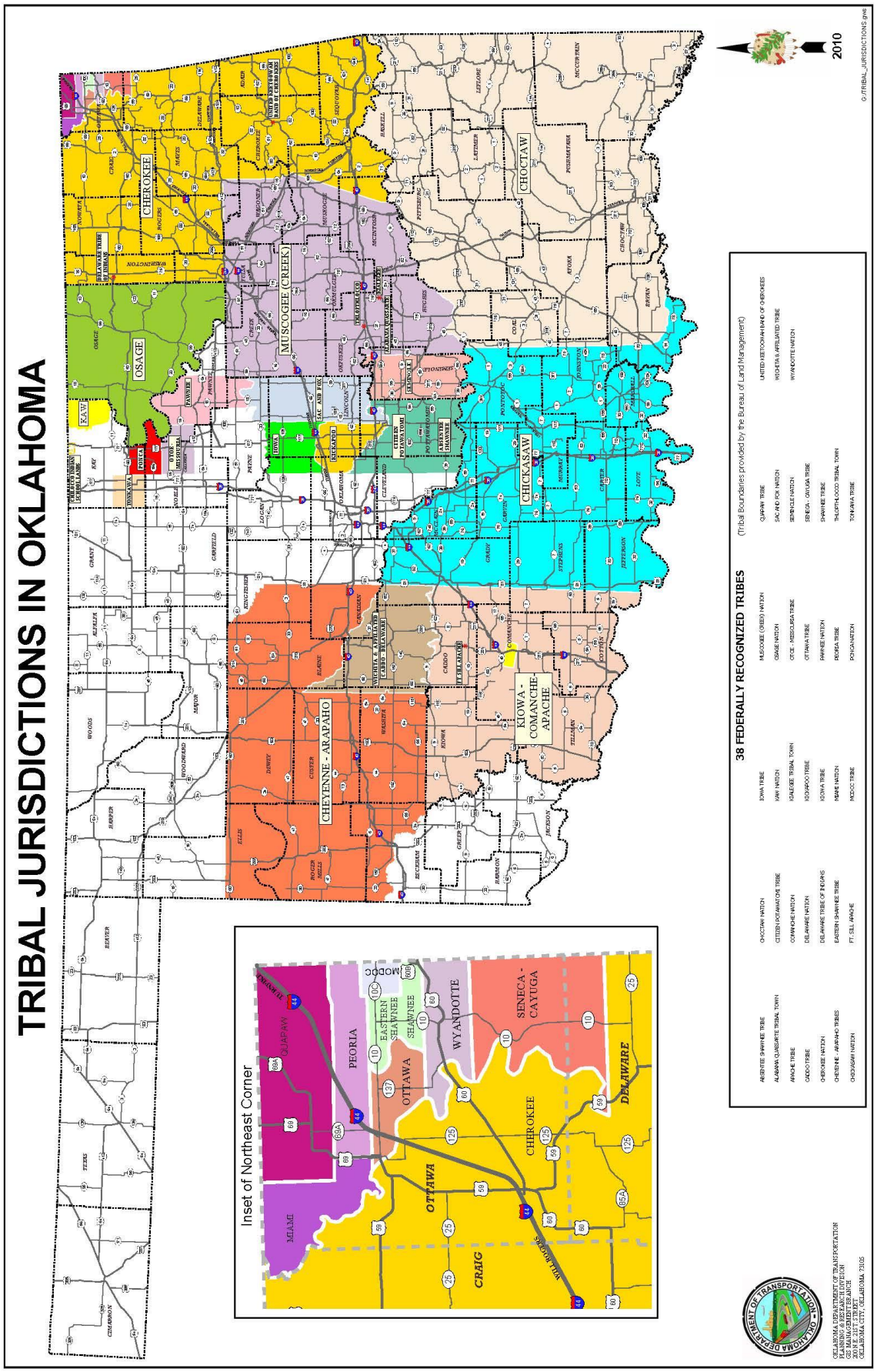
EXHIBIT A


TRIBAL JURISDICTIONS IN OKLAHOMA
2010
G:\TRIBAL_JURISDICTIONS.jpg
CHEROKEE
CHOCTAW
MUSCOGEE (CREEK)
OSAGE
KAW
CHICKASAW
CHEYENNE - ARAPAHO
KIOWA - COMANCHE - APACHE
Inset of Northeast Corner
MIAMI
JUAPAW
PEORIA
EASTERN SHAWNEE
OTTAWA
SHAWNEE
WYANDOTTE
SENECA - CAYUGA
DELAWARE
CHEROKEE
CRAIG
OTTAWA
WILL ROGERS
38 FEDERALLY RECOGNIZED TRIBES
(Tribal Boundaries provided by the Bureau of Land Management)
ABSENTEE SHAWNEE TRIBE
ALABAMA QUASSARTE TRIBAL TOWN
APACHE TRIBE
CADDO TRIBE
CHEROKEE NATION
CHEYENNE - ARAPAHO TRIBES
CHICKASAW NATION
CHOCTAW NATION
CITIZEN POTAWATOMI TRIBE
COMANCHE NATION
DELAWARE NATION
DELAWARE TRIBE OF INDIANS
EASTERN SHAWNEE TRIBE
FT. SILL APACHE
IOWA TRIBE
KAW NATION
KIALEGEE TRIBAL TOWN
KICKAPOO TRIBE
KIOWA TRIBE
MIAMI NATION
MODOC TRIBE
MUSCOGEE (CREEK) NATION
OSAGE NATION
OTOE - MISSOURIA TRIBE
OTTAWA TRIBE
PAWNEE NATION
PEORIA TRIBE
PONCA NATION
QUAPAW TRIBE
SAC AND FOX NATION
SEMINOLE NATION
SENECA - CAYUGA TRIBE
SHAWNEE TRIBE
THLOPTHLOCCO TRIBAL TOWN
TONKAWA TRIBE
UNITED KEETOOWAH BAND OF CHEROKEES
WICHITA & AFFILIATED TRIBE
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